S. Hrg. 98-270

REAUTHORIZATION OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON AGRICULTURAL RESEARCH AND GENERAL LEGISLATION

OF THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
UNITED STATES SENATE

NINETY-EIGHTH CONGRESS

FIRST SESSION

ON

S. 1263

A BILL TO AMEND AND EXTEND THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, AS AMENDED, FOR TWO YEARS

MAY 24, 1983

Printed for the use of the
Committee on Agriculture, Nutrition, and Forestry

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REAUTHORIZATION OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

TUESDAY, MAY 24, 1983

U.S. SENATE,
SUBCOMMITTEE ON AGRICULTURAL RESEARCH
AND GENERAL LEGISLATION,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:30 a.m., in room 328-A, Russell Senate Office Building, Hon. Richard G. Lugar (chairman of the subcommittee) presiding.

Present: Senators Lugar and Leahy.

STATEMENT OF HON. RICHARD G. LUGAR, A U.S. SENATOR FROM INDIANA

Senator LUGAR. The Senate Committee on Agriculture, Nutrition, and Forestry, Subcommittee on Agricultural Research and General Legislation, will come to order.

The subcommittee today will consider two bills to reauthorize the Federal Insecticide, Fungicide, and Rodenticide Act. S. 1263[1] is the administration's reauthorization bill introduced upon request by Chairman Jesse Helms. The other bill, H.R. 2785, was approved by the House of Representatives on May 17.

These reauthorization bills differ in only two respects. The House bill calls for a 1-year reauthorization period at an annual authorization of $64,200,000, while the administration's bill calls for 2-year reauthorization at $46,624,000, on an annual basis.

I anticipate that a broad range of issues may arise in today's hearing. I would simply ask at this time that each of our distinguished panel witnesses focus at least upon these two fundamental differences in order that a strong hearing record can be developed on these issues. We are well aware of controversies surrounding the FIFRA reauthorization. Last year, the full committee reported out comprehensive FIFRA reauthorization legislation. But this bill died in a lameduck session. I remain hopeful a similar confrontation can be avoided this year and the full Senate can move forward.

For those witnesses who have prepared rather lengthy testimony, I ask that you summarize your testimony briefly to 5 minutes, at maximum 10 minutes, with the understanding that your entire prepared statement will be made a part of the record. I'm hopeful that your cooperation with this request will free more time for specific questions from the subcommittee.

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[1] See p. 211 for a reprint of S. 1263.

I will close by thanking each one of you for attending today's hearing. I look forward to the testimony of our distinguished witnesses.

Just for the sake of the schedule today, let us note that we are commencing at 9:30. It would be the Chair's hope that we can proceed through a very substantial number of witnesses and conclude the hearing this morning. In the event that is not possible, we will start again at 2 this afternoon, and we will have a recess because both the Democratic and Republican Senators will be caucusing on important issues during the noon hour.

It is a very real pleasure to have as our leadoff witness, my colleague, the Honorable Paul Sarbanes, Senator from Maryland.

Senator Sarbanes, it is good to have you with us this morning. Please commence your testimony.

STATEMENT OF HON. PAUL SARBANES, A U.S. SENATOR FROM MARYLAND

Senator SARBANES. Thank you very much, Mr. Chairman. I will be brief. I prepared a full statement, if that can be included in the record.[1]

Senator LUGAR. It will be included in full.

Senator SARBANES. I really want to discuss a very specific issue as the committee considers the reorganization of FIFRA; and that is, I have introduced legislation requiring the Environmental Protection Agency to maintain and utilize an in-house facility for conducting biological tests on pesticides and other chemicals covered by FIFRA.

Until about 1 year ago, the EPA maintained such a laboratory for testing the biological effects of chemical products. It was located on the grounds of the Beltsville Agricultural Research Center, not far from here. It was capable of doing investigations in toxicology, microbiology, plant biology, and urology.

Over the years, this lab had done very important work in the routine screening of products, particularly disinfectants, where the products' efficacy had major public health implications. The lab was used to conduct special studies of products that have come into question, to periodically retest for degradation or random sample of products on the market, to do expedited tests for emergency registration requests, and to help establish scientific test standards and procedures to be used by outside laboratories.

I have attached a statement summarizing some of the major achievements of the Beltsville Biological Laboratory, and I would also like to include in the hearing record a number of letters from State environmental, State agricultural officials, as well as university researchers, attesting to the importance of the Beltsville laboratories.

I think it should be clear that the lab was well run, was well thought of, highly regarded, and was engaged in work with direct impact on the protection of the public health and the environment.

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[1] See pp. 73-86 for the prepared statement of Senator Sarbanes with accompanying attachments.

It is also important to note that the laboratory provided a useful function to industry as a central point for setting standards and for resolving disputes over ambiguous data.

In the face of this performance record, I was surprised and deeply concerned to learn in late 1981 of plans to close the biological laboratory. This laboratory served a unique and important national role. It was the only federally owned facility in the country equipped for, and experiencing and conducting, biological testing.

A number of protests were lodged, but, nevertheless, EPA proceeded to phase out the lab's work in early 1982 and to reassign its technical personnel to nonlaboratory positions. Without an inhouse biological laboratory, the EPA is incapable of carrying out independent objective tests to verify data regarding safety and efficacy being submitted by manufacturers. The EPA is unable to respond to emergency requests from States or other EPA units for tests on products involved in accidents or otherwise suspected of being unsafe or ineffective. EPA is incapable of responding to emergency registration requests where expedited testing is required.

My own view is that by closing down this lab, EPA is abrogating its responsibility for the protection of health and environment, which the Congress has entrusted to the agency.

The rationale EPA offers, the costs we are talking about here, is about $600,000, including salaries. And of course, most of the salaries are continued to be paid because personnel are reassigned elsewhere, often to nontechnical roles. Their rationale, I think, is seriously flawed.

EPA argues that the testing done at the lab duplicates testing done by private labs in connection with registration applications, an argument which ignores the need to be able to verify data to stop inaccurate data.

The recent news accounts about the ongoing case against IBT—Industrial Bio-Test Labs—points out the need to have this check of industry supplied data. I would like to submit an article discussing the IBT work and an editorial from the New York Times, called "The Scandal In Chemical Testing."

The EPA also contends that market forces can be expected to weed out products that are not affected. The problem with this argument is that the market forces could only come into play after a product is in use. In the case of chemicals, whose anticipated effects or lack of effects may have major health and safety consequences, reliance on market forces is clearly inappropriate.

For instance, between 30 and 40 percent of all disinfectants tested at Beltsville proved ineffective. And, of course, we have no way of prior testing these disinfectants. I want to submit some articles of hospitals who have used disinfectants proven to be ineffective.

The EPA has argued that much of the testing formerly done at the Beltsville lab can be replaced either by testing by the States or by testing on an as-needed basis by arrangement with other facilities. There are a number of problems with this approach; 47 States do not have a biological testing capacity. We will submit a number of letters from State officials in this regard.

Let me just quote two.

Thomas Irvin, the Georgia Commissioner of Agriculture, wrote to EPA, "There is absolutely no other facility available to the States which can act as a clearinghouse for biological methodology and provide to the States the biological support they must have if they are to undertake the routine assays of these health-related pesticides." And Virginia Secretary of Commerce and Resources, Maurice Rowe, pointed out to EPA that one can also question the wisdom of "closing an existing well-run facility versus gearing up many State laboratories to do virtually the same job."

The notion that they could contract all of the work out to private labs, I think, fails to recognize that many such labs are closely tied to clients in the industry to begin with. It does not provide a uniform central testing facility. I think this is very important. I think it is one of the reasons that the parties in the private sector have expressed concern about the closing down of this lab.

If you diffuse the testing either to the State level or on a contractual basis with private labs, you undercut the ability to have a central lab that does the testing and establishes the standards and whose clearance then represents for the industry in effect nationwide clearance. I think that's a very, very important point.

I know that you will be considering a number of difficult issues as you consider the reauthorization of FIFRA. A number of questions, of course, have been raised about the activities within the agency and the administration of this program. I do believe that this particular issue, small as it may be in money terms, as I said, about $600,000, is very important in terms of making sure that we have safe and efficacious products on the market. I believe this inhouse biological laboratory provided an important capability, was well run, highly thought of both by industry and users.

It could be reopened with very little difficulty, very quickly, at very little expense. The alternative is no such biological testing capability. I therefore urge the subcommittee to include in the legislation a requirement contained in legislation introduced, which a number of my colleagues have now joined in cosponsoring, requiring the EPA to maintain this facility.

Thank you.

Senator LUGAR. Thank you very much, Senator Sarbanes. All the recommendations you have made for enclosures will be honored, without objection. We deeply appreciate your testimony and your legislation.

Senator SARBANES. Thank you.

Senator LUGAR. Thank you for coming this morning.

I would like to now call Ed Johnson, Director of the Office of the Pesticide Programs, EPA. He will be our next witness.

At this juncture, the Chair would like to submit a letter written to the chairman of the Agriculture Committee, the Honorable Jesse Helms, from a number of Senators setting forth thoughts which they have about the FIFRA legislation. Without objection, we will include that letter in the record.

[The following letter was received by the committee:]

U.S. SENATE,
Washington, D.C., May 18, 1983.

Hon. JESSE HELMS,
Chairman, Committee on Agriculture,
U.S. Senate, Washington, D.C.

DEAR SENATOR HELMS: As you are aware, the U.S. House of Representatives has passed a one-year reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). We believe that growing public concern about the failures of the current statute to protect public health and safety makes a one-year authorization the most sensible course of action for the Senate. Therefore, we urge the Senate Agriculture Committee to follow the lead of the House.

We believe the Committee must deal with questions surrounding the validity of existing chemical company studies as soon as possible. Fifteen percent of all pesticides now on the market were registered with allegedly fraudulent data supplied by the Industrial Bio-Test Laboratory which is now the subject of criminal proceedings. The Committee would also address findings of recent GAO reports and a study by the House Agriculture Committee Subcommittee on Department Operations, Research and Foreign Agriculture which point out troubling deficiencies in the Act.

At this time perhaps more than ever before, the public needs to know that the Congress is reviewing this program and is ready to take action. However, a two-year reauthorization sends the false signal that all is well with the pesticide program.

The public has become acutely aware that the U.S. Environmental Protection Agency does not always offer the protection it was meant to provide. Similarly, many in health, farm, labor, consumer and environmental groups have told us that FIFRA, too, is inadequate.

Given the range of concerns about pesticide safety, we urge the Committee to report out a one-year reauthorization and immediately to begin considering major issues of public safety and possible legislative remedies.

Sincerely,

WILLIAM PROXMIRE,
HOWARD M. METZENBAUM,
ALAN CRANSTON,
CHRISTOPHER J. DODD,
JIM SASSER,
CARL LEVIN,
DALE BUMPERS.

Senator **LUGAR**. If you would proceed with your testimony, Mr. Johnson, it would be appreciated.

STATEMENT OF EDWIN L. JOHNSON, DIRECTOR, OFFICE OF PESTICIDE PROGRAMS, ENVIRONMENTAL PROTECTION AGENCY

Mr. **JOHNSON**. Thank you, Mr. Chairman.

Good morning. I am here today to support a simple reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. This request for a 2-year authorization without major amendment has been submitted to the Congress in the administration bill. It also includes a 5-year reauthorization for the scientific advisory panel.

As you are aware, section 25A rules cancellation actions, as well as major science policy decisions, have been directed to be reviewed by the Scientific Advisory Panel. We have found this to be a very useful forum for such in the past, and we were very disappointed when this authority terminated in September 1981.

We have revived the panel for a year. But we would like to see it revived by extension in legislation for 5 years.

In your letter to the agency, you asked that we review the history and status of major program elements in pesticide legislation, discussing the trends, accomplishments, and future plans, and we would like to do that.

We have dealt very extensively with this in over 35 pages of testimony, which I will not read, to everyone's great delight, I am sure.[1] However, we have prepared a briefing which we would like to give. I'm not sure that I can condense it to 5 minutes.

Senator LUGAR. Please proceed. I think it is important as a historical record in setting the stage for this hearing. Be concise, if you can, but please do proceed.

Mr. JOHNSON. Thank you. I will. I will be as concise as possible.

Breaking with traditional testimony and presenting the briefing to you, I think we can present the salient facts in a lot shorter time. And without further ado, I will move into this.

Copies of all these charts are attached to our testimony so that people who cannot see the charts or want to refer to them in the future will be able to use them from our testimony.

The first chart summarizes the major legislative efforts in pesticide regulation. The act goes back originally to 1910. And I certainly wouldn't dwell on the old amendments.

The major change, which is under the jurisdiction of this committee, is to require tolerances to be established to cover residues on food. And this I will discuss even though it does not come under this jurisdiction.

In 1972 there were major changes in the statute, making it a complete environmental statute. The major refocus was to make tests for registration of pesticides a test of unreasonable adverse effects as compared with the question of safety, which was the test in the earlier 1947 FIFRA. This causes the Agency to balance the benefits of pesticide use against the risks of use in reaching decisions about the pesticide. It also rounded out our authority by providing, for the first time, enforcement action against the misuse of a pesticide.

It also provided for classification to restrict it for general use or for certified applicators; it required that the agency go back and review all the pesticides that have been registered since 1947, bringing their data bases up to current standards and determining their current registerability under the new statute. And it made a change in the way people could support registration.

Registrants under the new statute had to support their registration with specific data, and it needed to pay compensation for the use of that data.

In 1975, under review by the Congress, it was felt that the Agency perhaps was a little too "hair trigger" on the risk side of the equation and was not giving adequate weight to the benefits. Therefore it developed the congressional committee and scientific advisory panel reviews to second-guess our decisions, to insure that we were dealing with real problems and had the best data and analyses available, and that we move forward in implementing our regulations under the statute, which are a very complex set of regulations.

We ran into some significant problems with the statute, and we came back to the Congress in 1978 and asked for additional assistance to help us with those problems. Conditional registration as a transition mechanism from old data requirements to the new was permitted under these amendments. A tougher task before we moved into formal reviews leading possibly to cancellation, was incorporated through the Grassley-Allen amendment, which required that rather than simply having toxicological testing in animals, the Agency also needed to look at exposure and the potential risk and insure that a prudent person would be concerned about that risk before moving forward on legal actions.

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[1] See p. 87 for the prepared statement of Mr. Johnson.

It also attempted to deal with the areas of data compensation and protection of valuable data generated by industry while at the same time making those data available to the public.

I might add that several of these areas continue to be issues today and have been the subject of much discussion and court suits. And in 1980, the Congress made some further amendments to FIFRA, reiterating the need for peer review of our decisions and providing for a two-House veto of our regulatory actions.

Our program generally can be split into two major areas. The first are the registration actions or other actions that allow new pesticides and new uses of pesticides onto the market in the first instance. This part of our program encompasses roughly half of our resources and the rate at which we must deal with these applications and petitions is not controlled by the Agency. These are sent in by manufacturers, by States, by government agencies, and others who are interested in using a pesticide on either a permanent or temporary basis.

On these charts I have tried to highlight some of the major elements of registration and emergency exemption programs. The darker colors in each case indicate the number of applications which were granted in the particular year. The lighter color indicates the number of reviews which were conducted by the Agency.

[The charts referred to above follow:]

FEDERAL LEGISLATIVE HISTORY FOR PESTICIDES

1910 — FEDERAL INSECTICIDE ACT

1947 — FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

- THE BASIC PESTICIDE LAW
- CONSUMER PROTECTION OBJECTIVES

1954 — "MILLER" AMENDMENT to Federal Food, Drug, and Cosmetic Act

1959 — FIFRA AMENDMENTS broadened its coverage

1964 — FIFRA AMENDMENTS increased safety concern

1972 — FEDERAL ENVIRONMENTAL PESTICIDE CONTROL ACT (FEPCA)

- MAJOR RE-FOCUS FOR FIFRA: "Unreasonable Adverse Effects"
- USE ENFORCEMENT
- CLASSIFICATION
- CERTIFIED APPLICATORS
- RE-REGISTRATION
- DATA COMPENSATION

1975 — FIFRA AMENDMENTS

- REQUIRED REVIEWS BY USDA, CONGRESSIONAL COMMITTEES, AND SCIENTIFIC ADVISORY PANEL (SAP)

1978 — FIFRA AMENDMENTS

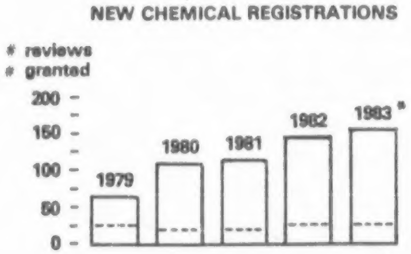
- PRIMARY USE ENFORCEMENT TO STATES
- "CONDITIONAL" REGISTRATIONS
- "GRASSLEY/ALLEN" AMENDMENT
- EXCLUSIVE USE OF DATA
- CLARIFIED PUBLIC ACCESS TO DATA

1980 — FIFRA AMENDMENTS

- PEER REVIEW
- TWO-HOUSE VETO

OFFICE OF PESTICIDE PROGRAMS

Reviews and Approvals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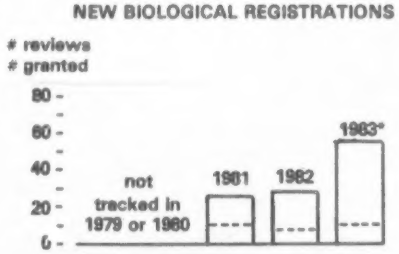
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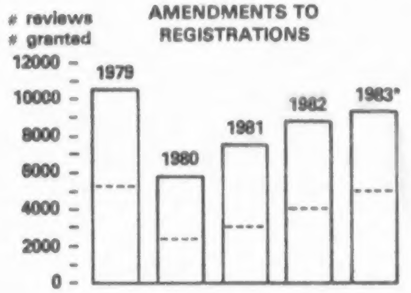
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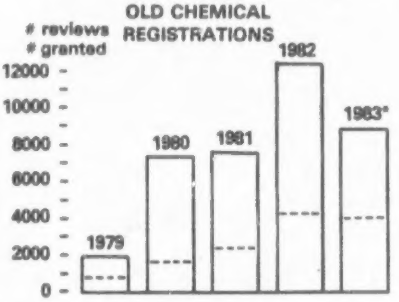
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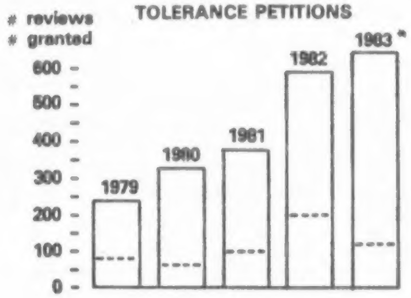
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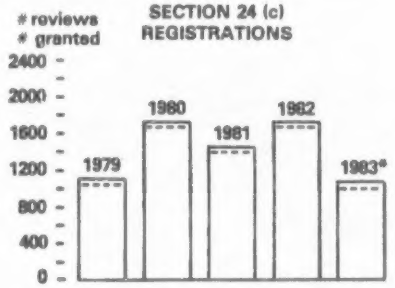
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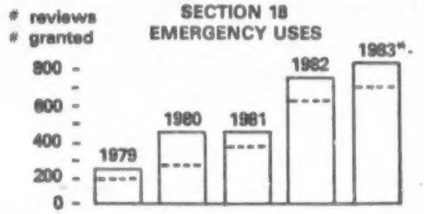
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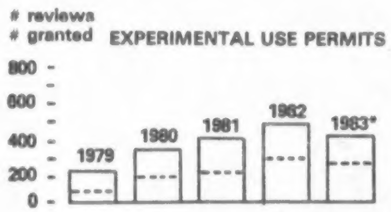
EXPERIMENTAL USE PERMITS

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OFFICE OF PESTICIDE PROGRAMS
Old Chemical Screening

SIX HUNDRED ACTIVE INGREDIENTS

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OFFICE OF PESTICIDE PROGRAMS

Special Reviews

PROGRESS IN SPECIAL REVIEWS

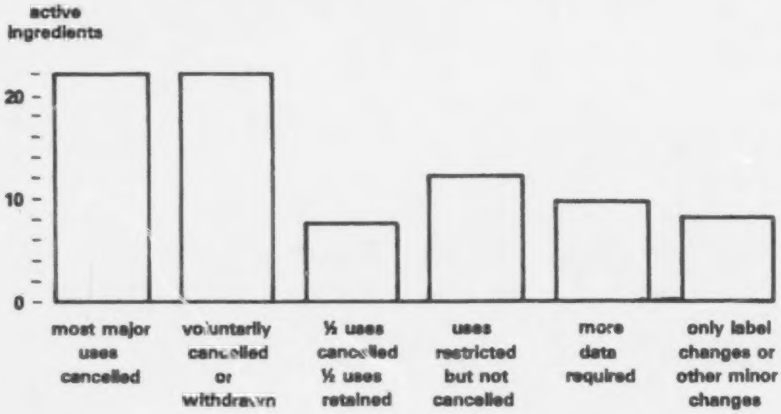
	1976 & before	1977	1978	1979	1980	1981	1982	1983
First	DDDD	DDDD	DDDD	DDDD	D	DD		
Position		DDDD	DDDD	DDD				
Document		DDDD	D					
Interim		D	DD	DDDD	DDDD	DDDD		
RPAR				DDDD	DDD			
Decision								
Final	DDDD	DDDD	DDDD	DDDD	DDDD	DDDD	DDDD	DDD[2]
Resolution[1]	DDDD	DDD	D	DD	DDDD	DDDD	DDDD	
	DDDD				DDDD	DDD	DDDD	
	DDD				DDD		DDDD	

"D" — one formal EPA decision

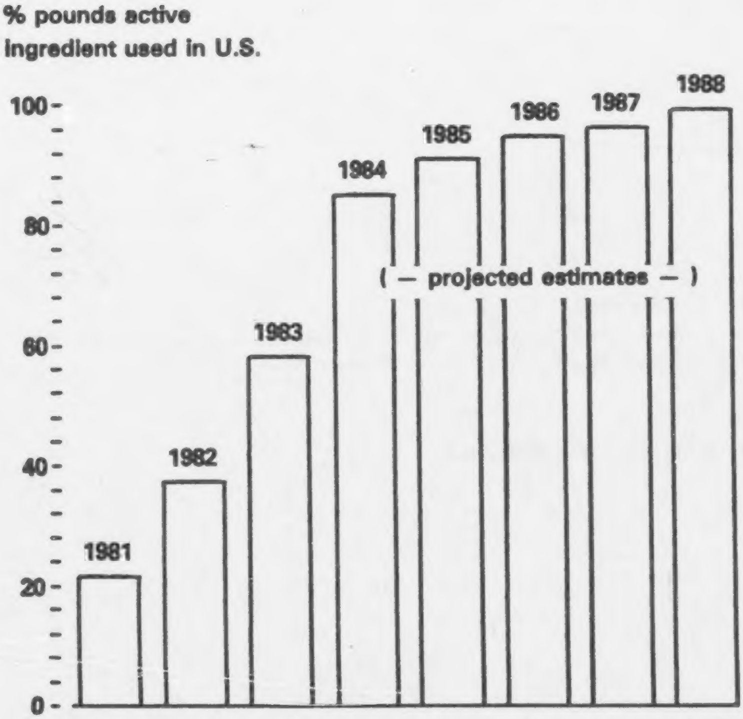
[1] — Final resolutions include returns to registration process, voluntary cancellations, EPA cancellations/suspensions, Position Document 4's, and negotiated settlements.

[2] — Expected this year.

OUTCOMES OF SPECIAL REVIEWS

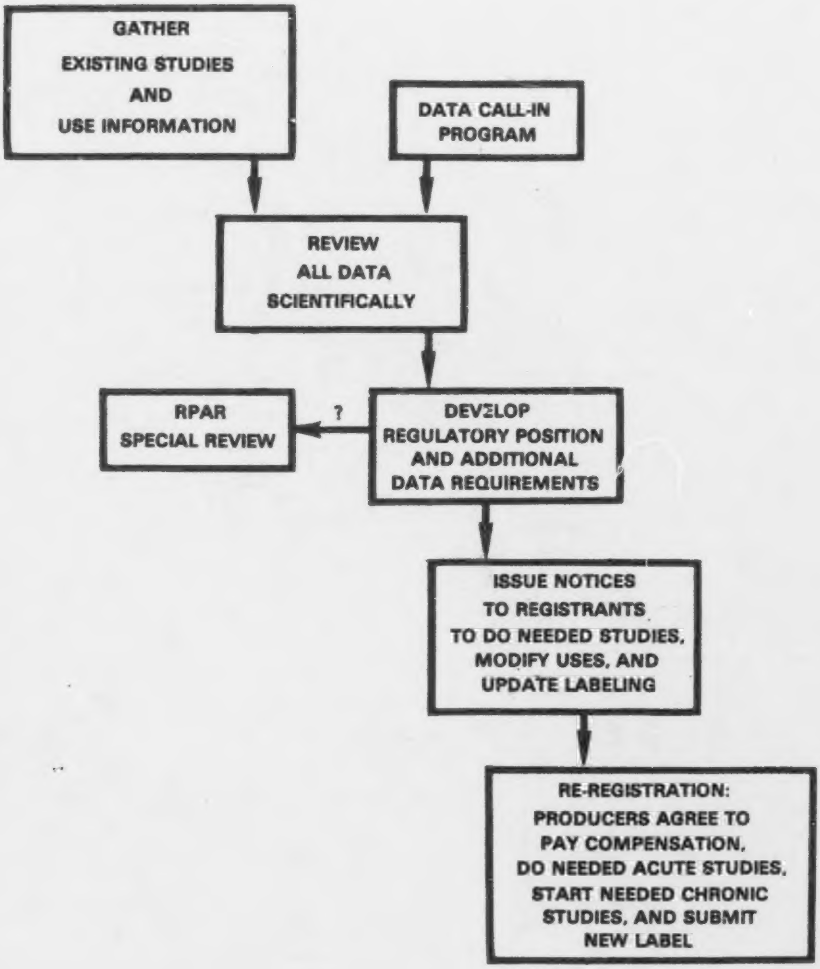


OFFICE OF PESTICIDE PROGRAMS
Data Call-In Progress



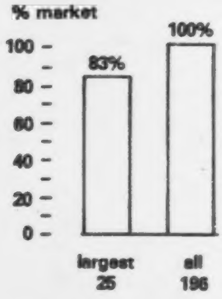
CUMULATIVE % POUNDS COVERED BY DATA CALL-IN PROGRAM

OFFICE OF PESTICIDE PROGRAMS
Summary of Registration Standards Process

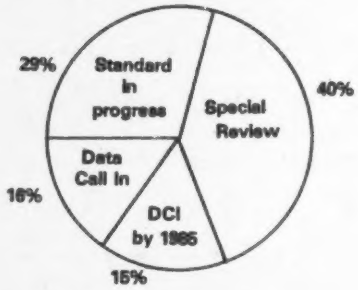


OFFICE OF PESTICIDE PROGRAMS
Progress in Reviewing Major Pesticides

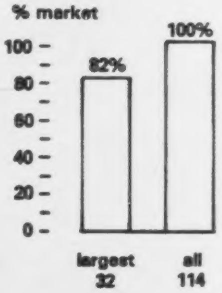
INSECTICIDES



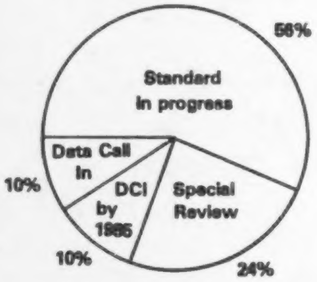
For the largest 25 insecticides:



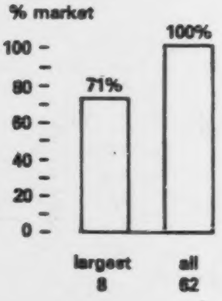
HERBICIDES



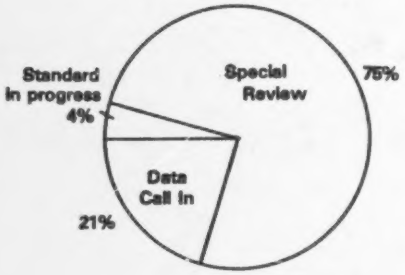
For the largest 32 herbicides:



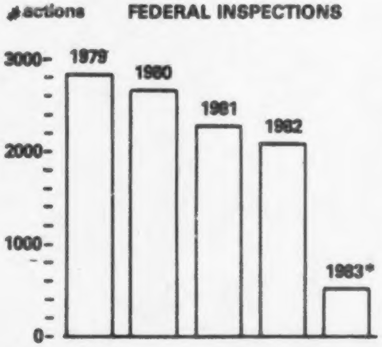
FUNGICIDES

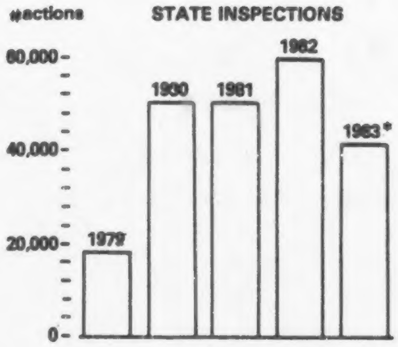


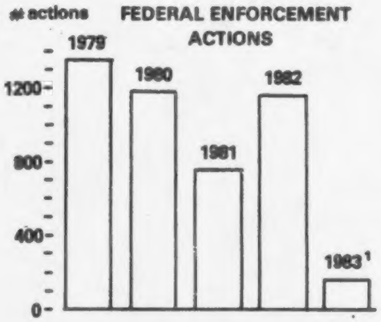
For the largest 8 fungicides:

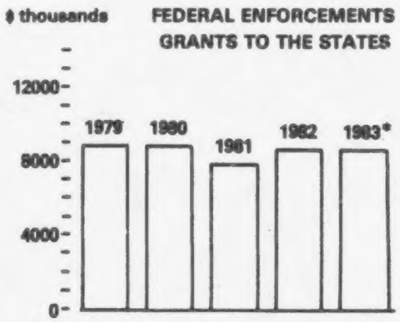


PESTICIDE
Enforcement Actions



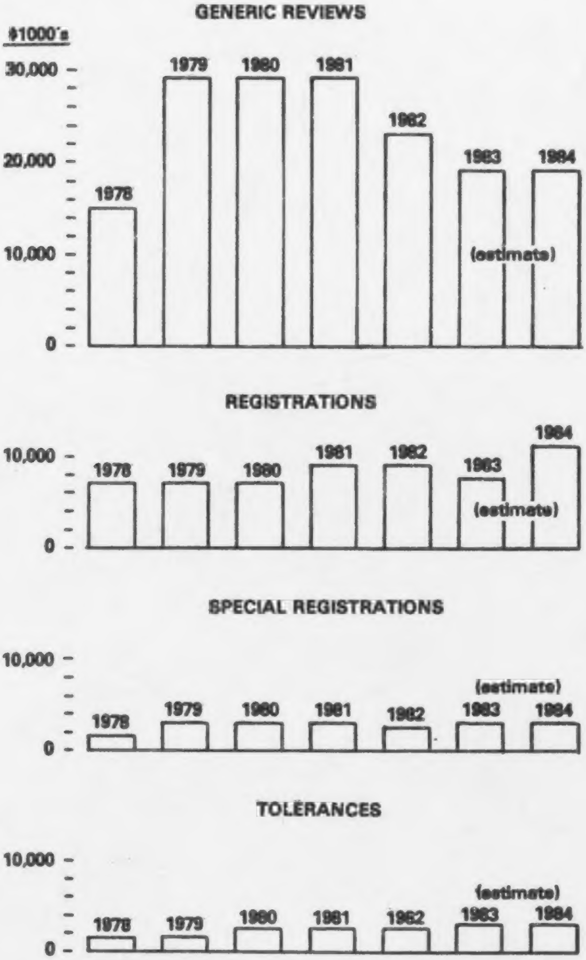






* - estimate
1 - first quarter only

OFFICE OF PESTICIDE PROGRAMS
Expenditures



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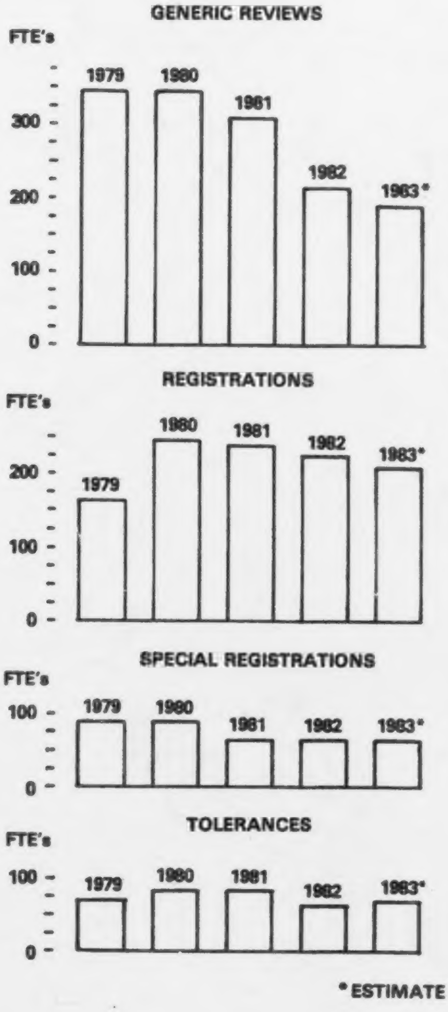
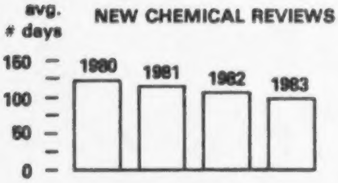
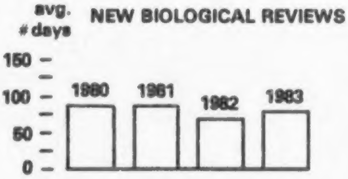
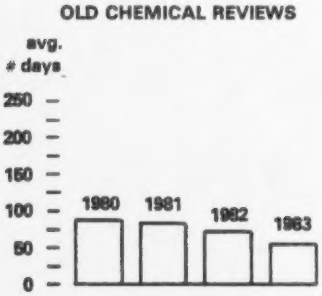
Full Time Equivalents

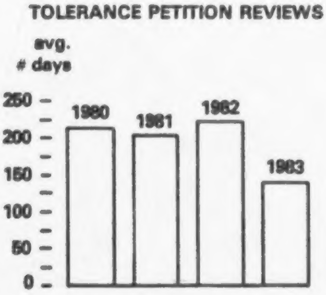


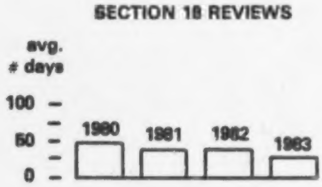
OFFICE OF PESTICIDE PROGRAMS
Processing Times

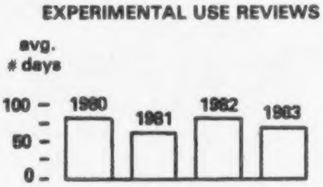












Mr. JOHNSON. We use the reviews as a measure of workload, because the number of times we have to look at an application determines the number of resources that must be used by the Agency to review it. And generally speaking, things go through two or three times before they are either finally approved or finally denied by the Agency. This is more true of new chemicals than it is for amendments to registration.

To summarize the significant trends here, we have seen a continuing upward trend in the development of new chemicals. These are the costly items to review for the Agency. And in discussions with the innovative manufacturers, we expect that these trends will continue in the future.

There is a long stream of new chemicals and new biologicals and I note an upturn in biologicals coming on line. Extensive research and development expenditures in the mid-1970's are now bearing fruition. So the Agency will have to continue to deal with increasing trends in this area.

A correlation to this is that once a new chemical is registered, it is expanded into new uses and new formulations. And we are seeing increases in amendments to registration that go along with this.

I might point out that this peak in 1979 is the result of an unblocking of the process by the conditional registration amendments which were passed by Congress, which permitted a smoother transition between old and new data requirements and resulted in a release of backlog. In old chemical registration, we see something similar in 1982.

We have developed some backlogs in this area in the Agency, and through a concerted effort to reduce backlogs in 1982, we got a lot of those out. And that is why you see a general upward trend in all these areas of registration.

This holds true also in tolerances. Tolerances are maximum legal residues that may remain on food commodities without it being considered adulterated. Much of this upward trend is because of the emphasis on minor uses of tolerances. And we are moving forward to try to deal with that in a somewhat more efficient way.

In 1975, the General Accounting Office reviewed our program of tolerances and came up with a number of suggestions as to how this program could be improved. We have submitted those to both the Science Advisory Board and the Agency as a whole. We received some very good suggestions as to how to improve our procedures both from an efficiency point of view as well as a scientific point of view. And we are in the process of implementing many of those recommendations at this time.

Another provision of the statute that has been looked at recently is section 24(c) registration. These are special local need approvals that are permitted by States. The Agency, as you will note, has turned down or not granted or disapproved very few of these section 24(c) registrations. The statute grants broad authority to the States and has only limited reasons the Agency may disapprove.

We are concerned about the high numbers, and we did an audit of this program which was just completed a few months ago. It showed several things:

One is that the majority of these registrations have been granted for legitimate local needs. It also shows that we may have overstated the numbers of our section 24(c)'s because States often do not grant them for an extended period but only for 1 year. So we should not be adding up all these columns for the total of some 6,000 registrations but rather should be subtracting out the ones that are no longer active. And we are taking steps to correct our numbers in this area.

We also found, however, that some people apparently are using section 24(c) registration—a limited number, but nonetheless, some—to gain earlier marketing of their pesticides while they are waiting for it to go through the more extensive Federal process.

Or in some cases where the pesticide has been unable to get through, they have gone to the States and by a series of 24(c) registrations have effectively gained a national registration. And we are taking steps to deal with that. It is a small proportion of the problem at the moment, but we see no reason to let it get any larger.

Similarly, we were concerned about the sharp increase in emergency exemptions that has taken place from 1979 to 1983—actually 1978 to 1982 is our historical base. And we have also conducted an audit of this program. We feel that there are several reasons for the increase, most of which appear to be legitimate:

No. 1, many registration applications were tied up in the Agency because of IBT questions, because of questions on our part, or because the data base did not support a long-term continuing registration. However, we felt that a 1-year use under controlled circumstances could be allowed.

Second, we noticed that there was an expansion in the basis for declaring an emergency. Economic situations, for example, the unavailability of a new compound for 2 years, became an emergency, rather than destruction by a pest. And we believe that we unintentionally became a little bit more liberal in how we interpreted "emergency" under this request.

We also found a few cases where companies actively marketed and promoted under emergency exemptions. And again this was a handful of cases compared with the total numbers that we have used.

But we think we need to take some steps in the emergency exemption area to bring some of these things under control: a redefinition of what constitutes an emergency, a look at whether new chemicals ought to be available and some tightening up of the criteria. This year we will be reviewing and making necessary revisions in, our rules governing section 18's. Again, there's been a slight upturn in experimental use. The Agency has been working very hard to reduce our processing files.

And I will just say that generally there's been a downward trend in all of these areas over the years as we have streamlined our processes and improved our management capabilities.

Concomitant with this we have also reduced the backlog of the registrations in the Agency essentially to zero in most cases. But backlogs are increasing this year. We have three court cases and have in fact negotiated some of the necessary licensing provisions that Congress provided for in the statute. We believe that backlogs will again begin to go up because of those court suits; second, because of the rising workload and the stable resource picture in this program; third, because of skill imbalances which we have not yet been able to accommodate, which reduces our efficiency in some areas.

I think we made the major breakthroughs that we are going to be able to make in registration in terms of management and personnel improvement. I think the future improvement in productivity in this program will come from improvements in management of our information resources and better, more efficient, handling of data. We are in the process now of taking our basic study data, which is in hard bound form, and by the end of 1984 this will be converted into an automated data system, which should improve our utilization of the data, and also make it easier for us to make these data available to the public.

Senator LEAHY. Mr. Chairman, I'd like to ask a question.

Senator LUGAR. Yes.

Senator LEAHY. In doing that, are you making sure that you are dealing with laboratories that you can actually rely on? What are you doing to weed out invalid kinds of data?

Mr. JOHNSON. Well, we are weeding out those kinds of data in our registration standards program. This program is simply an improvement in our data management practices.

Senator LEAHY. Are you making sure though that you do not have something of that nature lurking in there? Are you reviewing all the work through all your programs——

Mr. JOHNSON. Yes, we are.

Senator LEAHY [continuing]. To make sure that you are not being snookered again?

Mr. JOHNSON. Yes. And we are also carrying out quality assurance programs through the laboratory audit program which has gone back, in fact, to past years to many of the laboratories that have done health and safety testing. I won't say that anything would make it impossible, but it will certainly reduce the possibility.

Senator LEAHY. Can we rest assured in this committee that it is going to be extraordinarily unlikely that we will see something like that?

Mr. JOHNSON. Yes, Senator Leahy; I believe that is the case. IBT has done several things. It has put us more to work on problems that we can be aware of and made our scientists a little more aware. Second, we have put a laboratory audit in place and actually gone out and looked at those laboratory studies at the laboratory itself. And in cooperation with the Food and Drug Administration, we are looking for good laboratory practices at laboratories that do health and safety testing. And, finally, I think IBT has also upgraded the level of quality control of laboratories that submit these studies to us. They can see that these can lead to real problems with their studies and with registration and the expansion of uses. It's increased the quality control of that.

We also are automating our data base with respect to uses of chemicals, precautionary statements, and products containing active ingredients, to provide a data base on line to the agricultural community to help provide assistance to them as to what's available. We expect to make some further improvements in automation.

Let me turn briefly now to the old chemicals. These are programs, as I mentioned, that provide for use of new chemicals, new products, and new applications of pesticides. The second half of our program, which we do control within the Agency, is a review of old chemicals.

In the mid-1970's, we were faced with 1,400 active ingredients which, when grouped together, comprised 600 active ingredient groups that needed to be reviewed. The program was actually started in 1973 and 1974, and moved along in fits and starts as a data gap-filling program. And it was moving forward under the presumption that all the data that we had received were properly done in the laboratory and properly reviewed. As we moved the program forward in 1976, we discovered through the drug case and the IBT investigations that this indeed was not the case. And we stopped the program and took a new approach to it. So we were set back several years from those findings in those two cases.

Basically we had to devise a strategy for dealing with these 600 active ingredients. We needed to, first of all, determine priorities for dealing with these chemicals. The first priority was given to identifying problem chemicals where someone had provided evidence or there had been a review which indicated positive evidence of adverse effects which made it reasonable for us to presume that the pesticide ought not to be registered. Second, we had to devise a method for gathering data to fill gaps in the data base; third, we needed to develop a way of reviewing old chemicals which did not have suspected adverse effect associated with them, but rather just needed to be reviewed to determine what their registration status ought to be; and, finally, we discovered that many labels were out of date, and we had to devise programs to bring labeling up to date.

We ran these 600 active ingredient groups through a screen to determine whether there were questions that caused us to presume that they should not be registered. And through this process, in the initial clips, there were 45 such chemicals. And over a period of a few years, we added almost another 45, so that 89 pesticides were elected for special review on the basis that there existed some evidence that their registration status was in question.

With respect to the other chemicals we had no data to indicate that they should be taken off the market. But on the other hand, perhaps only 10 percent of these were supported by a data base that would be deemed adequate by today's standards. So we had to move forward with these chemicals basically to fill the data base and review the data to determine whether the chemical ought to remain registered or whether it posed unreasonable problems in today's context.

Let me just turn now to the special problem chemicals that were identified. These 89 were identified here. As a first priority, the Agency moved forward with these because these were demonstrated problems. And we felt that is where our first priority ought to be. Before 1976, these chemicals were dealt with through fairly lengthy cancellation proceedings which lasted for several years and cost everybody several million dollars. Among the first resolutions back then were the old chlorinated hydrocarbons, and they were resolved after lengthy hearings.

In 1975, we began to work in a different way to do business on these chemicals that would be less resource intensive and involved scientific discussion rather than legal discussions at the earlier stages to try to resolve issues. And we came up with a rebuttable presumption against registration program or our special review program. This consists of issuing a notice that this chemical was suspect and needed to be looked at carefully in terms of its benefits and risks.

Our priorities in the mid-1970's and late 1970's were to get these identified and get them into the process. Therefore you see that there were a lot of decisions made in the early years to issue the first position document.

The priorities shifted as we moved along in time, and we began to try to move these chemicals toward final resolution, so that our focus shifted into interim decisions which are decisions proposed for comment by the Science Advisory Panel, the U.S. Department of Agriculture and the public. And once they were reviewed and comments received, moving them down into the final resolution area.

We are also asked why we haven't any more chemicals in the rebuttable process for these years. I think the reasons are very obvious. Our first attempt was to find the problems, and therefore out of the 600 active ingredient groups, we found what we thought were identifiable problems. And until we got additional data, we were not going to find any more. We found most of these in the beginning of the process.

Second, we began a data call-in program to gather data to help us make better decisions on the other chemicals. And until those data are received, it is unlikely that we are going to find further adverse effects information to initiate new procedures. However, as we review those chemicals, we fully expect that we will be initiating new special reviews.

Let me point to some of the outcomes of the special reviews. I think they demonstrate that we have taken a fairly evenhanded approach to our review of these old chemicals. In the case of 44 chemicals most major uses were canceled, voluntarily canceled, or withdrawn. That's about half of the 89. For some, some of the uses were canceled and other uses retained. When we finished our review of still others, the uses were restricted but not canceled. In some cases we found that we had inadequate decisions to make final decisions and we required data be resubmitted by the manufacturer to maintain his registration. And in a few cases, approximately eight, we found that only label changes or other minor changes were necessary in order to obtain the registrability of the chemical.

One of the major programs that was made possible by the 1978 amendments, which required that companies agree to fill data gaps to provide this data on a timely basis or face suspension of their product, was the opportunity to provide a data call-in program to fill data gaps. We identified 600 chemicals on a priority basis, to see the order in which we should move. And we took the chemicals with the highest probability of exposure first and began to send notices to registrants to develop data to fill data gaps in the chronic effects areas, oncogenicity, reproductive effects, and teratogenicity areas.

Manufacturers were put on time schedules to develop those data. And this shows the progress we are making in this program.

By the end of this fiscal year, we expect to have 60 percent of the pesticides used in the United States under testing. By 1985, we expect to have over 90 percent of the chemicals under testing in terms of the pounds that they represent. This program I believe is moving along well and should establish the data that we need to bring our data gaps up to snuff and to make final decisions.

Now, with respect to these other 600 chemicals, we have also instituted a review process which is relatively straightforward.

First of all, we gather existing studies and use information from our files and other sources. If the data from the data call-in program are available, we need those also and do a very scientific review of the data to see if any gaps are shown other than those we had anticipated in the data call-in program, or whether any unreasonable adverse effects, need for label changes, restrictions of use, and so forth, are called for. And we develop a regulatory position which clearly states what we feel the continued registrability of that chemical is.

If it appears to raise an adverse effect, it goes into the EPA special review program. And this, as we move further along with reviewing old chemicals, will be generating new chemicals for the special review program. However, if they do not issue any special concerns, then we issue notices to registrants to do needed studies and come back to the Agency for reregistration of their product.

The reregistration occurs when the producers agree to pay data compensation, when they have completed the needed acute studies, the studies that are needed in the short term, when they have agreed to start needed chronic or long-term studies and to submit new labels, which is extremely important in this program.

Right now we have had to modify this a little bit because of the recent court suits. And there's uncertainty as to how registrants may support their registrations because of the unconstitutionality findings in one of these cases. And until we get that sorted out, we are only requiring the manufacturers to commit to doing product studies which we think is very important from the health and safety review in amending labeling.

We will go back to them by the time this is straightened out.

Let me show you some of the progress we have been making in reviewing major pesticides.

As I said, we have put the pesticides in order for review.

We reviewed first those pesticides which have uses that encompass the possibility of high exposure, those that are used on a large number of food crops, those that have large poundage volume; in general, those that are used in ways that expose a large number of people. And while I have left some of the things like rodenticides and disinfectants off this chart to simplify it a little bit, I think we can see that a very few pesticides account for the vast majority of the market.

For example, in insecticides, the largest 25 selling pesticides account for 87 percent of the market. We are getting at a large proportion of the potential problem by assigning proper priorities. And in the case of these 25 insecticides, I would like to point out that 40 percent of the poundage represented by those 25 has already been reviewed or is under review in the special review program. And we, in fact, will finish those before the end of 1985. For 29 percent of the poundage, we already have a registration standard, one of the reviews that I just spoke about, in progress or completed; 16 percent of the poundage is now subject to data call-in under the data call-in program. And we expect that the remaining 15 percent of the poundage will be covered by the data call-in program by 1985.

We see similar statistics for 32 herbicides, which comprise 82 percent of the market. A substantial portion of these are being covered by standards at the present time.

With respect to fungicides, the largest eight fungicides account for 71 percent of the market. As you can see, 75 percent of the poundage has been covered by chemicals in this special review program; 21 percent are already in data call-in, and 4 percent have standards already in progress.

In the enforcement area, the Congress dictated in 1978 that we make a substantial shift from Federal enforcement to primarily in-State enforcement actions. And you can see the shift here in the decrease in Federal inspections and significant increase in State inspections, which are supported in large part by Federal enforcement grants to the States.

I want to point out that this is not a 1 to 1 tradeoff. Each unit over here accounts for 20 times of each unit over here.

Federal enforcement actions have been variable but have remained fairly high in comparison with numbers of inspections that have been taken, and Federal enforcement grants have been fairly level, although there is a small decrease planned for 1984 of approximately $1 million.

Let me turn quickly now to the resource situation over the years, starting first with dollar expenditures. These are broken down in terms of our major budget decisions in units that correlate with the areas I was talking about before.

Generic reviews is the controlled part of our workload of reviewing existing chemicals. Registration, special registration and tolerances are the budget units that deal with the uncontrolled workload where we need to deal with it as it comes in the door, and have less discretion as to whether we deal with it or not. In these areas we have had slight upturns across the board in order to deal with increasing workloads and to reduce our processing times.

In the area where we have actually controlled the budget ourselves, we have had some reductions in dollar value and have tailored our programs to meet the trends in funding those areas. This is an area that Senator Leahy often inquires about, and essentially the rate of output of registration standards up to some point where we can't do any more in 1 year, is a function of the amount of resources devoted to it, and the program scales up and down accordingly.

Looking at our onboard strength in terms of personnel in the same areas, we've had fairly stable personnel in those three areas—minor ups and downs. We have accommodated the increased productivity through some contract work with the extra dollars that were programed through, but it was predominantly through efficiency improvements in these program areas.

In the generic review area we have suffered some substantial personnel reductions. Several things were key in doing this. One is that we tried to take these reductions with a minimum loss of scientific personnel. So while we have suffered, I believe, about a 30-percent reduction over this period, the scientists in the hazard evaluation division were reduced by only 12 percent. So we have taken a disproportionate share of this in nonscientific personnel, and we have been very careful to try to do that. But we cannot control who leaves and we are faced with a hiring freeze.

The people who leave sometimes leave us with a unfortunate distribution of talent. And one of the things we are suffering from right now is a skill mix imbalance; for example, too many biologists, and not enough chemists. But we believe with the stable budget that is offered by the 1984 Presidential budget, we will again be able to rehire from outside the Agency and no longer be on a tight hiring freeze. So that we will be able to rebalance our staff over the next year. So we see some ways out of that. But it is causing us some problems right now.

Essentially, the President's proposal and reauthorization that we are seeking for 1984 is a stable continuation of the 1983 budget into 1984. And we believe that that will enable us to plan and to carry out our programs on a much more stable basis than those budgets submitted in previous years. We look forward to that stability.

I will be pleased to answer any questions you have. And thank you very much for giving me the extra time. I appreciate that.

Senator LUGAR. How does the data call-in situation work? Can you describe—you have talked about this. I have a thought of people calling in information on the telephone. But physically what is involved in this?

Mr. JOHNSON. The first thing we do is to screen through our data files to determine where there are data gaps in significant studies, cancer, chronic effects, reproduction, and teratology. Where those gaps exist, we then send very formal letters to each registrant advising him that he has 90 days to agree to develop those studies and to schedule their submission to the Agency.

If he does not come back and agree to do it within 90 days, or if he fails to meet the schedules then under section 3(c)(2)(B), the Agency is authorized to suspend his registration until such time as he does come into compliance.

A second feature of the program that is important is that under section 6(a)(2) of the statute the manufacturer is required to identify for the Agency any studies that show an adverse effect. And of course we will be looking at those studies ourselves to see whether they show any adverse effect that would cause us to put that chemical immediately into the special review program.

Senator LUGAR. You heard the comment on the legislation proposed by Senator Sarbanes. Do you have a comment about the Beltsville facility?

Mr. JOHNSON. Yes, I do, Senator.

We have given that laboratory a very extensive review before deciding to scale back our activity out there. I think that, first of all, the issue of the effectiveness of disinfectants is certainly something that I fully share Mr. Sarbanes' concern over. We have to be sure that these things work. And it is not immediately apparent to the people who are using them whether they work or not, because they are destroying viruses and bacteria which are invisible to the naked eye. And it's only after something adverse happens that they realize that the disinfectant didn't work.

There are a number of ways of insuring efficacy, and there are a number of issues concerned.

In reviewing the Beltsville laboratory activities and the scale at which they were being performed, we determined that we were really providing a false measure of security to the public. Due to the scale on which the program was running, we were testing very few products. And with the types of failure rates we were finding for some products, it was apparent that there were many batches of ineffective products reaching the marketplace despite our testing.

But our testing was causing assurance in the hospital community that these products they were getting were all OK. In light of the budget constraints, it was impossible to expand the laboratory up to the scale of what was required to do a really topnotch job of testing many batches of products.

I also would like to point out that the failure rate that Mr. Sarbanes mentioned, 60 to 70 percent, at Beltsville lab, is simply because we tested products we expected to fail. We knew who the manufacturers were who appeared to have great variability in their production practices, and we went after those products. So those samples were biased.

When people test on a random basis, the fail rate is more on the order of 10 to 12 percent, as I understand. So there is a much smaller proportion on ineffective of products reaching the marketplace than Beltsville might have shown.

Finally, there's a question about the test method itself. When applied by people that are inexperienced, there is a great deal of variability of what one finds. And it is hard to interpret those tests in a legal action. In all the years we have been running the Beltsville lab, we have not canceled a pesticide based on ineffectiveness. But as I said, the level of testing permitted other untested batches to go into the marketplace.

So we are attempting to work with the Association of Chemists to develop and define the test method so that, No. 1, it can be used in a reproducible fashion by investors; and, No. 2, we really know what the meaning is of killing or not killing the test bacteria for actual use situations in the hospital. So those are two areas that we feel are very important to address before anybody rescales testing activity in this area.

In order to augment our information, we are trying to set up user networks with people who have an opportunity to test these on a case-by-case situation in the hospitals, much as we have done with the National Pest Control Association for rodenticides.

Second, we are looking toward funding the Florida lab and North Carolina lab as a way of augmenting our testing to get short-term indications as to what's happening in those areas. And finally, we are looking at some potential for industry testing in order to assure that quality control procedures are maintained and requiring quality control tests to be submitted to us on a periodic basis by the manufacturers, thereby transferring the cost of this to the industry. And finally, if fees for various forms of Federal programs are implemented, which is something we are moving forward with under the administration's directive to charge user fees for things that are eligible, it is possible that we could set up a testing program that would be in fact supported by industry since it is as important, I believe, for the industry credibility as it is to the consumers of pesticides.

So those are some of the considerations that we are looking at right now. And I think that we have to make a decision on the laboratory because otherwise we would have maintained what I believe is an untenable status quo position by continuing the testing. We in fact forced the issue to the forefront and forced people to address the issue and come up with real solutions rather than solutions that I think don't fill the bill. That's essentially been our rationale in dealing with the laboratory situation.

Senator LUGAR. You favor 1-year authorizations, 2-year authorizations, or what length? And at what level of funding?

Mr. JOHNSON. Mr. Chairman, we certainly support the administration's recommendation for request for a 2-year extension because it increases the stability in the program to have some of those things behind us.

Senator LUGAR. And you favor the level of funding therefore under S. 1263 at $46,624,000?

Mr. JOHNSON. The level of funding which was requested matches with the appropriation which was sent forward by the President in January. As has been discussed publicly, Mr. Ruckelshaus will be reviewing the Agency's budget. And while he has made no determination as to what he is going to do, it could conceivably result in an amended 1984 budget.

The House has tried to accommodate an increase in the potential. And the Office of Management and Budget says that it is not concerned so much about the level of authorization, whether it stays at the administration level or whether it moves to the House level, because what really determines the amount of money the Agency receives is the appropriation, not the authorization. And therefore they do not have a strong position.

Senator LUGAR. What action is your Agency taking with regard to the Federal legal situation in the St. Louis jurisdiction? And how do you expect that to be resolved?

Mr. JOHNSON. We are doing two things. Since the judge did not grant our motion for clarification of the stay at the district court level, we are moving as rapidly as we can to request a stay in an appeal to the Supreme Court. The stay can be granted by one Justice. And we are very optimistic that we will get the stay because three other cases of a similar nature were decided in favor of the constitutionality of those provisions.

Those cases went to the Supreme Court, and they did not grant cert on those cases supporting implicitly the finding that those sections were constitutional. So this is the first of the findings that declared those unconstitutional.

Senator LUGAR. When will requests be made?

Mr. JOHNSON. Ed, can you help me out on that one?

Mr. GRAY. It is really up to the Department of Justice.

Mr. JOHNSON. We have provided that information and the necessary documentation to the Justice Department. It could come anytime in the next few weeks. We also are working with the industry attorneys to determine that we interpret that case as broadly as possible.

In the first instance, we took a very narrow construction of what was allowed, given that decision, because we did not want to be in contempt of court or open ourselves up for more criticism in the use of registration methods that were not supportable. Since that time, the industry has made some proposals to us in ways the cases could be interpreted more broadly; and we are looking at those so that we can, in fact, continue to operate as normally as possible even while we are waiting for a stay.

Senator LUGAR. Mr. Johnson, I deeply appreciate your testimony this morning. Senator Leahy wanted me to convey likewise his appreciation to you. And I would unanimously consent to grant that, being the only Senator here.

Senator Leahy's statement and the letter that he wishes to insert will be made a part of the record prior to your testimony.[1]

But in the comment he made to me, as he had to part for other business, he pointed out that you have been a very stable figure throughout all of our hearings. As you recall, Senator Leahy was chairman of this subcommittee throughout the 1978 legislative period and I was the ranking Republican member at that time. And the events that you have mentioned with regard to 1978 are remembered well by all of us. You and your colleagues mentioned at the time that 50,000 applications were piled up, and it is to your credit and those who have worked with you that that record of success that you have pointed out this morning has become manifested. We are grateful to you.

We appreciate your testimony and the historic record that will make our hearing record much more complete.

Mr. JOHNSON. Thank you. It was a pleasure to be here. We couldn't have done our changes without the help of Congress, and I'm thankful for the efforts you all put into it.

Senator LUGAR. Thank you very much, sir.

[The following was subsequently received by the committee:]

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, D.C., August 10, 1983.

Hon. RICHARD G. LUGAR,
Chairman, Subcommittee on Agricultural Research, and General Legislation, Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: In response to your letter of June 13, 1983, we have enclosed answers to your additional questions following your hearing of May 24. I apologize for the lateness of our response; we apparently had a misrouting problem in the Agency.

We stand ready to provide any further assistance you or your staff may require.

Sincerely yours,

EDWIN J. JOHNSON,
Director, Office of Pesticide Programs.

Enclosure.

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[1] See p. 71 for the prepared statement of Senator Leahy.

Question 1. Why has there been a decrease in RPAR activities in the past two years?

Answer 1. EPA has achieved much of its original purpose by dealing with most of the older existing pesticide registrations that were identified in the mid to late 1970's as potentially posing unreasonable risks. The newer pesticide registrations have more complete, more recently developed data bases, and are less likely to trigger an RPAR proceeding. Thus, it would be unusual, and in fact an indication of flaws in the process, if the number of RPAR's initiated continue to be high, since the process is designed to correct past errors or problems. Additional RPAR candidates are expected to emerge from the currently ongoing registration standards program which requires registrants to generate data to bring data bases up to current standards and requirements. It is important to recognize that the Agency is coming to the conclusion of a most significant major step in reviewing an accumulation of 25 years of pesticide decisions as directed by the Congress.

The Agency has stated publicly that changes are needed to the regulations governing special reviews in order to bring the rules into compliance with the 1978 amendments to FIFRA, to speed the time it takes to complete an intensive review, and to reduce the costs to the Government and other participants. We believe that the public is afforded a greater level of protection when we are able to reach the earliest possible resolution to questions to a pesticide's potential risk. We hope to have the proposed regulations out for public comment this calendar year.

Question 2. Why have the more recent RPAR final decisions been returns to registration rather than cancellation?

Answer 2. When RPAR became operational in 1976, one of the Agency's first tasks was to identify potential problem chemicals and to then rank them in order of greatest risk based on the extent of suspected health effects data, the severity of the suspected health effects and dimensions of exposure to the population. For example, food use chemicals, because of the public's widespread exposure to them, were ranked high, while industrial use chemicals were assigned lower places in the ranking scheme. Health effects of great concern, such as potential for causing cancer, were ranked highest so they would be dealt with on a priority basis.

As the Agency completed reviews of the higher priority chemicals in the late 1970's, we were able to focus on the lower priority chemicals in the early 1980's. It is therefore reasonable that many of these chemicals have retained their registrations with certain important "strings" attached, such as additional use and exposure restrictions, cancellation of certain uses or types of formulations or applications, and additional data requirements. The increased understanding of the RPAR process by the regulated industry, and their increased understanding of the need for and willingness to accept restrictions on the uses of their chemicals rather than battling for years over the outcome, has facilitated many of the recent RPAR decisions, as has introduction of better tested, more effective alternatives to older pesticides. Please note that not all of the more recent RPAR decisions have been returns to registration. EPA's final decision on toxaphene was to cancel most major uses of the compound. Similarly, our proposed EDB decision does not return most currently registered uses to the registration process.

Question 3. What administrative changes does the Agency plan as a result of the recently completed audit of Agency activities under sections 18 and 24(c) of FIFRA?

Answer 3. Regarding section 18 emergency exemptions, the Agency plans four actions in accordance with the audit's recommendations. First, a special group has been assigned the task of closely examining the "crisis exemption" provisions of the regulations, to see whether they should be revised to prevent improper use. Second, this group will settle upon a definition of "emergency" which better reflects the intentions of the Congress and which precludes any use of emergency exemptions to circumvent the section 3 registration requirements. Third, the Office of Pesticide Programs (OPP) has stopped sending telegram notifications of section 18 decisions to the States through the normal EPA communications procedures, which took as long as three weeks. OPP now sends the notifications immediately through Western Union, so that States can act within a day of EPA's decision. Fourth, the Registration Division is working out a method for tying the frequency of emergency exemptions given for a particular pesticide on a particular crop to the priority given to tolerance petitions for that chemical and commodity. Fifth, EPA is reiterating the purpose of and our expectations regarding section 18 with the States. In this connection, the Association of American Pesticide Control Officials (AAPCO) will be distributing a packet of pertinent background and policy documents prepared by EPA to State officials undertaking new responsibilities in pesticide regulations who have not been previously acquainted with the section 18 process. In addition, the Agency plans to request comments on the regulations implementing section 18 and make necessary changes through the notice and comment rulemaking process.

Regarding section 24(c) special local needs registrations, the Agency's administrative actions in response to the audit fall into two categories: revising and updating Agency files; and preventing circumvention of section 3.

In updating Agency files, we are adding error checks to the input of records into our computer files, maintaining better control of the physical location of section 24(c) files in the Agency, re-organizing the processing of 24(c) information, and most importantly, purging files of section 24(c) registrations that have expired, been cancelled, or been withdrawn. EPA will soon be sending to each State, for verification, a list of 24(c) registrations which we believe are no longer in effect. We will then reflect the correct status of those 24(c) registrations in our records.

Then, to prevent circumvention of section 3 by section 24(c), EPA will use a computer analysis of the registrations which are verified as still in effect, to determine which of them provide for the same uses of the same pesticides in many States. Because a pesticide use cannot be a "special local need" if it is simultaneously provided for in many States, EPA plans to effectively "require" registrants to apply for section 3 registrations for such uses by issuing a section 3(c)(2)(B) letter requiring the necessary data.

Question 4. The number of emergency exemptions granted under section 18 of FIFRA has increased over the past years. Explain this increase.

Answer 4. Typical of a "permit" program, experience and familiarity with the program on the part of State agencies and their support groups is leading to increasingly greater utilization. However, this does not necessarily indicate that the program is being abused. The increasing numbers of requests have come about through a step-wise progression, albeit fairly rapidly. Information on activities under the section 18 program are being communicated between States to a greater degree each year. In addition, EPA publishes *ex post facto* notification of section 18 actions in the Federal Register, which helps to keep the States as well as the general public advised of these activities. As the audit of the program demonstrated, the increase in requests for section 18's also resulted from the fact that the Agency refused to grant permanent approvals for several categories of chemicals, such as those whose data base was largely invalidated because of the Industrial Bio-Test (IBT) scandal, but we were willing to grant limited, controlled approvals on a one-year basis while pertinent questions were being answered. This situation leads to an increase in section 18 requests for several chemicals.

Whereas early section 18 requests (in the early to mid 1970's) were generally submitted when there was *no* registered alternative available, the tendency in the late 1970's up to the present is for a State to determine whether an emergency exists based on comparative factors. Thus, although a pesticide may be registered for the use in question, be generally effective for the use, and also be available in sufficient quantities to treat the affected area, it may not be capable of controlling a critical outbreak resulting from unusual weather conditions or unsuspected pest populations or migrations. When such a situation occurs, the State agency will address the registered alternatives and explain why they will not effectively alleviate the emergency situation and, therefore, why the unregistered pesticide use is necessary.

EPA initiated a project to get more information on why many registered alternatives were judged to be ineffective. Responses received from contacted registrants were carefully examined and considered. In almost every case, the registrant readily admitted that this product did not work at its optimum 100 percent of the time and that variations in weather, soil type, geographical location, and agricultural methods as well pest resistance to certain chemicals or chemical groups always greatly affect the results realized from pesticide use. Several people discussed the entire question of comparative effectiveness and the quirks of nature that affect and alter the day-to-day performance of a pesticide. One extension entomologist wrote in to indicate he felt that too much emphasis is frequently placed on achieving an extremely high percentage of control (over 90 percent).

Subsequent to this project and repeated prompting by EPA, most states began to include more informative explanations relating to registered alternatives. Therefore, although the number of exemption requests continues to be high and to be increasing, we have a better understanding of the basis for the requests. There will always be situations where the registered product will not perform as well as usual; that is when an emergency exemption may be found justifiable. The Agency will continue to examine incoming requests for valid ineffectiveness claims and will contact the involved registrant if needed.

Question 5. Have scientific reviews been compromised by the so-called "cut and paste" problem? What action has been taken to address this situation?

Answer 5. For reasons explained below, it is not yet known whether Agency reviews have been compromised, but the question is being investigated. A number of steps have been taken to address the situation.

When the "cut and paste" issue was first brought to my attention, I immediately met with the Director of the Hazard Evaluation Division to examine the nature and extent of the situation. After a series of meetings with the Director, and between the Director and his staff, we ascertained that "cut and paste" practices appeared to be limited to one section of one branch of the division, and within that section to only a few individuals. More importantly, examination of the reviews in question led us to believe that these individuals generally did perform their own reviews, but to write reports more easily, these reviewers simply took statements from the investigators' reports with which they agreed instead of restricting them. Unfortunately, proper attributions of such statements were not made. Thus these so-called "cut and paste reviews" maybe more accurately termed "cut and paste reports."

However, these preliminary findings are based only on conversations with individuals in the branch and division. Moreover, the one case examined in depth did show that an apparent adverse effect in the test animals had gone unnoticed by both the investigators and the Agency's reviewer. Therefore, I believe these findings need to be further substantiated, and we are reassessing the pertinent studies.

All reviewers have been instructed that cut and paste practices are unacceptable operating procedures, and all such actions should cease immediately. If a reviewer agrees with an investigator's statements, he may use them in quotation marks and indicate his agreement. He may not plagiarize report language.

To assure the credibility of our review and remove uncertainties raised by this issue, we have taken several steps to address problems of quality assurance both retrospectively and prospectively. Retrospectively, we have employed a contractor to go back through reviews of several years and conduct a two step examination. In the first step, a large sample of reviews are being examined to identify apparent cases where cut and paste practices were used. This phase of the project is nearly complete. The second step is a detailed re-review by toxicologists to determine whether the cut and paste actions compromised the scientific quality of the review. This phase will begin in several weeks and will require two to three months work.

Prospectively, we are considering several options to improve quality assurance procedures associated with the review process for the most important of the chronic and subchronic health effects studies. In addition, I have established an audit function on my own staff to select samples of various program activities and follow them through the entire office of Pesticide Programs decision process to assure that operating policies and procedures are not violated, and to institute corrective action if they are.

Question 6. When will the data base which has been eroded by IBT data be replaced?

Answer 6. On July 11, 1983, the Agency released a report summarizing the status of the joint program by EPA and Health and Welfare Canada to review the validity of pesticide studies conducted by IBT. A copy of our report has been supplied to the Subcommittee.[1]

Our report notes that of the 140 pesticides tested by IBT for health effects significant to our regulatory decisions, a large majority have some non-IBT data available while only a handful of pesticides still registered in this country are wholly supported by IBT data. The report identifies over 100 valid IBT studies and another 200 invalid studies which have been or are being replaced. An additional 140 studies were identified as unnecessary because the type of test is no longer required or the pesticide is not registered or used in the United States. For the remaining studies, which have not been replaced or identified as unnecessary, the Agency is in the process of notifying registrants of their obligation to commit themselves with 90 days to providing replacement studies or face suspension of their registrations. The actual time involved in replacing a study depends on the type of tests, and varies from several months up to four years to design, carry out and evaluate a chronic feeding study. However, this does not mean that the uncertainties created by the IBT case six years ago will linger for another four years.

In general, we found that high volume use chemicals tested by IBT, which present the highest potential for exposure to pesticide users and the general public have been largely accounted for in terms of available alternative data or commitments to replace IBT studies. Many of the pesticides most likely to receive our notifications this summer appear to be minor use products for which registrants will accept voluntary suspension rather than invest in further testing. At this point it appears that the status of invalid IBT studies has been brought under control and are well on their way to being resolved. The remainder of the IBT program consists of tracking commitments and evaluating replacement studies in case adverse effects requiring regulatory action are revealed, in the same way we are assessing all pesticide chemicals registered prior to the mid-70's regardless of the laboratory which conducted the supporting studies.

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[1] The report has been retained in the committee files.

Question 7. What is the scope of laboratory audits conducted by EPA under the National Laboratory Program? What have audits revealed about the quality of testing in laboratories?

Answer 7. The National Laboratory Audit Program was established to provide the Office of Pesticide Programs (OPP) with assurance of the reliability of scientific data submitted to the Agency to support registration of pesticide products. It is a joint program with the Food and Drug Administration (FDA), and in its present form also involves EPA's Office of Toxic Substances and the Pesticide and Toxic substances Compliance Monitoring Staff. Enclosed is a copy of the Memorandum of Agreement describing in detail the responsibilities of the three EPA program offices and the types of inspections and audits they conduct. Also enclosed is a copy of our interagency agreement with FDA.[2]

In a GLP inspection, FDA is examining the laboratory's facilities and equipment, the qualifications of the staff, and whether established procedures for the conduct and documentation of studies are being followed, and are in compliance with FDA's standards. In a data audit, EPA is examining the so-called "raw" data of a study, which includes records of daily observations, feeding schedules, reports of tissue examinations and the like, to see if this data supports the conclusions of the final report submitted to the Agency. In some cases, EPA may request reports of GLP inspections on certain laboratories, without directly participating or auditing studies. GLP reports can alert EPA to the potential need for auditing studies produced by a particular laboratory.

A data audit is not an evaluation of the laboratory as such. It is FDA's specific responsibility to provide the laboratory with a written report of inspections and data audits together with any recommendations they may have on laboratory practices.

In general, we have found the large majority of laboratories to be in compliance with GLP standards and to be producing scientifically valid studies. Where problems were identified in the first two years of the program, subsequent inspections have found the laboratories to be in compliance, or to be no longer conducting the type of testing relevant to FDA or EPA regulation. Aside from IBT, only three cases of possible malfeasance have been identified out of 150 inspections and/or audits.

This year we are conducting about 40 inspections and/or audits, and are planning about 60 for fiscal year 1984. Some laboratories are chosen for audit at random, but priority is given to facilities which conduct large numbers of pesticide studies, or which have had problems in the past.

Question 8. What is the potential impact on the registration process if the Monsanto case is upheld? How is the Agency preparing to deal with this possibility?

Answer 8. If the Monsanto case is upheld, it will be more difficult and complicated for applicants to apply for registration. It will be more difficult, but not impossible, for applicants to cite specific studies to meet data requirements, and to get permission to use those studies which they themselves have not generated. We have recently issued a notice to all registrants explaining how to apply for registration; these procedures are consistent with current court orders. I enclose a copy of this notice for the Subcommittee's information.[2] Please note that the "horizontal line" between producers of technical product and formulators contained in FIFRA § 3(c)(2)(D) is still in effect, and formulators who purchase a registered technical product need only submit or cite data pertaining to the end use product, thus continuing to relieve formulators of the responsibility to submit or cite the expensive chronic feeding studies when they purchase a registered technical product.

The Justice Department has appealed the District Court ruling in the Monsanto case. As you know, our request for a stay of the opinion pending review on the merits was recently denied. As you may be aware, the Courts have ruled in the Agency's favor in three other cases involving these same constitutional issues.

Question 9. What is the status of the national pesticide monitoring plan?

Answer 9. FIFRA section 20(b), enacted in 1979, requires EPA to develop and periodically revise a national plan for monitoring pesticides. A plan implementing the original National Pesticide Monitoring Program was published in 1971 by the Federal Working Group on Pest Management (FWGPM). This plan was followed by EPA and other Federal agencies during the 1970's. The FWGPM was abolished in the late 1970's. In 1980, OPP/EPA completed a revised monitoring plan taking into account the new types of pesticides then (and now) in use. The new plan was never adopted, and the old plan lapsed in several areas due to conscious resource reductions in monitoring.

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[2] Retained in the committee files.

More recently, Congressman George Brown has encouraged OPP/EPA to develop a new monitoring plan, and we have agreed to do so, although it is not yet clear to what extent this activity will be supported by the 1984 budget. The new plan is to be completed by October 1984 and in effect by January 1985. According to discussions with our oversight committee in the House, the plan should provide for maximum use of the work of other agencies, both State and Federal, by trying to obtain conformity and aggregation capability among these groups, rather than start a brand new, large Federal program. We believe that this approach makes sense and look forward to the new plan.

Question 10. Dr. Davies, a member of SAP, testified to the importance of human monitoring in evaluating the effectiveness of the pesticide program. What is your response to this testimony?

Answer 10. Dr. Davies is concerned because OPP has greatly reduced and will soon discontinue entirely its adipose tissue sampling and analysis program. As part of the National Pesticide Monitoring Program, since 1970, EPA has been collecting human adipose tissue samples and analyzing the samples for residues of about 20 chemicals, most with some pesticidal relationship. Although that monitoring activity has been very fruitful, OPP discontinued the tissue sampling program in the last several years because of higher priority regulatory needs. Many of the pesticides that EPA sought to measure in tissue samples during the 1970's have been examined by the Agency from a regulatory standpoint, and most have been restricted, cancelled or voluntarily withdrawn from the market. The utility of continued sampling and analysis for the original 20 chemicals now seems limited, except perhaps to measure and document trends in residue levels over time. We believe it will be more productive to change our human monitoring activities to include a different, larger group of chemicals that are now more widely in use. Thus, OPP is cooperating with the Office of Toxic Substances (OTS) in an expanded chemical analysis of selected composite specimens of human adipose tissue. Through these exhaustive analyses, we will look for residues of a wide variety of pesticides and other chemicals. The first results of these new monitoring efforts are expected in early FY 1984. As you may know, the pesticide program's House oversight committee expressed concern about the Agency's pesticide monitoring activities during our reauthorization hearings earlier this year. The committee asked through their Committee Report that EPA prepare a new pesticide monitoring plan by October 1984, and begin implementing its provisions by January 1985. We will be considering the matter of adipose tissue sampling as we develop this new plan during the coming year.

OPP is also changing its human monitoring emphasis from tissue analyses to include broader types of exposure studies. For example, the Program presently is funding the following activities by the National Pesticide Hazard Assessment Program:

Farmworker exposure studies;
Field and epidemiologic studies;
Youth in Agriculture studies;
Training for medical personnel;
Application technology reports; and
Emergency response.

In addition, OPP is participating with the HHS National Center for Health Statistics in the Health and Nutrition Examination (HANES) for Hispanics, and is maintaining the Toxicant Analysis Center at Bay St. Louis, Mississippi.

Senator LUGAR. The Chair would like to call now a panel of four witnesses: Maureen Hinkle, National Audubon Society; Jorge Manring, National Wildlife Federation; Jay Feldman, National Coalition Against the Misuse of Pesticides; and Jacqueline Warren, Natural Resources Defense Council.

If those witnesses will come to the table, we will proceed with our testimony.

Good morning.

May I ask you to testify in the order that I introduced you. That will be Maureen Hinkle, Jorge Manring, Jay Feldman, and Jacqueline Warren, in that order.

Ms. Hinkle.

STATEMENT OF MAUREEN HINKLE, REPRESENTING THE NATIONAL AUDUBON SOCIETY

Ms. HINKLE. Thank you, Mr. Chairman.[1]

Audubon appreciates this opportunity to testify on differences between the House and the Senate versions of the reauthorization of FIFRA. Not surprisingly, we support the House version for an increase of $8 million over the President's request. The reason for this is that we believe there's a serious problem of public confidence in EPA's pesticide program.

Despite the fact that this is the best presentation, the jazziest presentation, that EPA has presented here, I think that it may have been intended to show to you progress that has been made in FIFRA and the pesticide programs since you last took a look at it. We really appreciate the fact that you are looking at this again, because you do come to it with a long history of detailed knowledge.

We believe that the chaos, as opposed to the alleged stability, in the pesticide program has been highlighted recently by the disclosure of fraudulent testing of a high percentage of pesticides now on the market. And as a result, we believe that public trust can be restored only by direct congressional attention to problems that are now a matter of every day headlines.

We believe that a 1-year reauthorization is all that is required because of the complexity of the problems which need addressing before the year is out. Because of the urgency of the budgetary process, 1 year is all that is really necessary.

In support of the increase in funding to $64.2 million, as opposed to $46.24 million, we would like to call your attention to our April 6 testimony before the House, that went into great detail on the resource implications of EPA's budget cuts for the past few years. Since that testimony, a confidential memo surfaced in the chaotic days following the departure of several EPA officials which describes the "impact of fiscal 1982 turbulence."

Mr. Johnson—and I quote—said, about the budget cuts of the past 2 years:

> We have repeatedly had our plans reduced to shambles by multiple rounds of reductions. When significant changes of this sort occurred for both 1982 and 1983 budgets, we tried to reflect them realistically through reduced program outputs. It now seems clear that these output projections may be too optimistic, which has implications for program plans, performance standards, and employee morale.

This statement goes to the qualitative performance of the program, to the work burden, which has been reduced by deregulation of industry.

This memo was written a year ago. If the cuts are instituted that are proposed in the Senate version now, and the backlogs referred to remain, there will be no action, for the procedures, the processes and the reorganization incorporating these changes are now in place.

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[1] See p. 137 for the prepared statement of Ms. Hinkle.

The new administrator can alter these changes, but they are, as Mr. Johnson's memo of a year ago states, "many and pervasive." The flexibility of the new administrator to change these far reaching and deep policies, and restore the trust that he wants to restore, will not be available to him without an increase in funds. We also believe there's no substitute for congressional oversight and legislative correction.

I would like to emphasize the fact that the data that we are relying on now and the data gaps that we have, are in some cases intentional. Several memos call attention to collusion between industry and EPA to keep the data gaps as broad as they have been. Without good data, there can be no regulatory action. And yet good data is in the public good and for the good of the companies who produce good data. Having bad data and good data mixed up really punishes the companies that happen to be conscientious. And there have been several, even those whose studies were involved in the Industrial Bio-Test Labs.

One realization of EPA's past policies has been called EPA's "million dollar boots." What this means is that industry spends millions of dollars on its tests. EPA spends millions of dollars evaluating their tests. The result is often a recommendation to put on gloves, put on rubber boots, or a respirator. The regulatory outcome of this exercise was to hide the process in the registration standard system. Industry tells EPA what tests they want to conduct and EPA does not need to spend lots of time and lots of resources on the evaluation.

The other side of this picture is public information. If the public doesn't have any information, we can't determine which is good data and which is bad data, and which registrations to recommend and which not to.

At the present time there is such a vast measure of distrust. I am getting too many people who ask: What do you recommend? You must tell us something because we don't trust anyone else. This is really unfair to me, and it is unfair to have distrust of government come to such a point.

The upshot of the *Monsanto* decision at this point is that no information is being released by EPA. The St. Louis judge has ruled that public disclosure of submitted data is tantamount to permitting the public to share in the regulation of the pesticide industry. So we operate with this decision for the following year.

I have attached to my testimony several studies on IBT that's more recent than much of what has appeared in the press. The value of these studies is to show that there is a large percentage of data gaps that now exist. They can only give the public a large measure of anxiety about EPA's handling of the pesticide program. We believe that the integrity of the program is at stake, and that the only way to deal with it decisively is to amend FIFRA as quickly as possible.

Senator LUGAR. Thank you very much.

I'd like to call now on Dr. Manring.

STATEMENT OF DR. JORGE MANRING, REPRESENTING THE NATIONAL WILDLIFE FEDERATION

Dr. **Manring**. Mr. Chairman, I appreciate the opportunity to appear before this subcommittee on behalf of the National Wildlife Federation and its more than 4.2 million members and supporters.

The House has just passed H.R. 2785, which extends authorization of FIFRA to the 1984 fiscal year. A wide range of important proposed changes have been introduced in the past 2 years, and the House Committee on Agriculture has committed itself to studying these proposals thoroughly in order to promote speedy House action to improve the public and environmental protection afforded by this law. The National Wildlife Federation calls upon the Senate to consider proposed amendments to FIFRA with this same sense of urgency.

However, the National Wildlife Foundation believes that these issues can be resolved in the 1-year timeframe adopted by the House and therefore does not agree with the 2-year extension of the statute as proposed by Senate bill 1263.

The NWF is particularly interested in four issues regarding FIFRA. These include the guarantees of health and safety data disclosure as provided by section 10(d), the establishment of a quality control review board for pesticide health and safety data, the need for FIFRA specifications to remove from the market pesticides shown to be inadequately tested, and the retention of adequate States' regulatory authority as provided by section 24(a).

The NWF is especially concerned over the contested issue of health and safety data disclosure. The NWF feels that the provisions specified in section 10(d) of FIFRA are entirely consistent with the fundamental objective of the statute, that is, the protection of the public and the environment from the use of pesticides, and that any changes limiting this disclosure seriously compromises public and environmental protection from pesticides.

The pesticide industry has made strong efforts to limit public access to health and safety data, arguing that such disclosure reveals trade secrets that result in severe economic harm. Although the industry has not demonstrated such an occurrence, the NWF believes there are compelling reasons for maintaining section 10(d) unchanged, even in the event that some economic disadvantage could be ascribed to the guarantees under this section.

The EPA faces a difficult task in predicting the social peril due to the pesticide's use solely on the basis of experimental testing data submitted by the manufacturer of the product in support of its registration. Data are sometimes scientifically inconclusive, leading reasonable scientists to arrive at different interpretations. Furthermore, the manufacturer will often design and report studies in the manner most favorable to his product. It is possible to manipulate experimental conditions in order that a test give biased results.

Only close scrutiny of raw test data—and I underline raw test data—and evaluation of experimental design can reveal this type of bias. After a pesticide is approved, the EPA has only rarely had the time and resources to reevaluate the original health and safety data in light of changing evaluational criteria. As a result, questionable industry interpretations can remain undetected for years. As was indicated at FIFRA hearings in 1975, 15 years elapsed between the original regulatory decision to accept the manufacturer's interpretations that the pesticide heptachlor did not cause cancer in rats and later evaluations of the same data, plus independent experimentation, which indicated that heptachlor was very likely to be carcinogenic. Readily available registration health and safety data on this pesticide may very well have hastened the eventual cancellation of heptachlor; absent such data, public exposure to this carcinogen would likely have continued far longer.

The open scientific community attempts to minimize this kind of problem—by independent scientists—by subjecting one scientist's research results and methods to formal and informal review by other scientists. When health and safety pesticides data cannot be disclosed, data and test methodology can never enter significant peer review channels and it is thus not subject to scrutiny by independent scientists. That this can be a real problem is best underlined by the fraudulent health and safety data submitted on behalf of over 200 pesticide registrations by Industrial Bio-Test Co.

The public disclosure of health and safety data on pesticides would also promote the assessment of such data by independent public interest groups. Although the industry may belittle such benefits, contending that few consumers or independent scientists would actually read disclosure data, even limited added participation in the review of health and safety data can improve safety decisions. The fact that consumer representatives and independent scientists lack the time or resources to scrutinize all health and safety data is an insuffcient reason to deprive them of the opportunity to analyze what they consider important. Furthermore, in the light of rapidly expanding toxicological knowledge and of an increasingly informed and concerned public, the probability of public use of pesticide health and safety data is considerably enhanced. The threat of scrutiny by critical outsiders should motivate industry and EPA scientific personnel to analyze health and safety data more carefully.

Although NWF feels that the advantages of the disclosure of pesticide health and safety data are strong components of the safety net for public and environmental protection, it feels that there are additional serious problems with EPA procedures for health and safety data scrutiny. It is very well for the public to be allowed to examine data in its own health interests, but if that data is fraudulent, public disclosure of this information has not really served its purpose.

NWF specifically calls attention to the case of Industrial Bio-Test Laboratories whose proven fraudulent data has been used to support, and still supports, the registration of 212 pesticides. While this deception was discovered by an FDA audit in 1977, press accounts indicate that only recently have the EPA and FDA begun to establish the extent of the fraud.

In this case, the generation of original data was doctored for the reports eventually submitted to the EPA and FDA. Access to the raw test data is therefore as important as it is to disclose registration health and safety data.

There is no current estimate as to the potential threat these pesticides have represented to the American public. Perhaps there is no reason for alarm. However, the procedures employed to review health and safety data submitted on behalf of pesticide registrations have some obvious problems. These difficulties may be the result of insufficient personnel, excessive workloads for time allotted, inadequately prepared staff, or possibly all of these. Whatever the reason, it is quite likely that the present undermanned, underfinanced EPA will not be able to guarantee that such gaps in its data scrutiny won't occur again. In fact, in connection with the problem with Industrial Bio-Test data, it has taken more than 5 years of study to begin to determine the extent of the fraud with pesticide data. NWF is concerned that public and environmental health are being compromised by inadequate pesticide health and safety data and that these review procedures deficiencies have been compounded by recent reductions in EPA Office of Pesticide program staff and operating funds.

NWF strongly recommends that an autonomous pesticide health and safety data review board of independent health scientist specialists be established through FIFRA to be financed by fees levied on the data generators to determine the adequacy of health and safety data submitted on behalf of pesticides. Such a review board should be involved on a full-time basis as a quality control check on EPA inspections of past and present pesticides health and safety data.

Because there are specific health data required for the registration of a pesticide, it follows that the lack of this data on behalf of a pesticide should constitute grounds for nonregistration of the chemical. The fraudulent data generated by Industrial Bio-Test Labs submitted on behalf of pesticide registration applications involved tests to ascertain pesticide carcinogenic and teratogenic properties, and potential for inducing other genetic damage. The lack of data testifying to the safety of these pesticides with respect to genetic effects is alarming enough to demand that those products not certified as harmless in this regard be removed from the market.

Under the current FIFRA, there is no provision to remove an inadequately tested pesticide from commerce. The NWF feels that this is a serious deficiency in the statute in light of the Industrial Bio-Test scandal. The NWF therefore urges the Congress to remedy this situation in the interest of public and environmental health. Specifically, NWF recommends that FIFRA specify that pesticides found inadequately tested should be removed from the market until appropriate health and safety tests have verified its recommended use as safe to public and environmental health.

Under section 24(a), the States are granted the authority to regulate pesticides more stringently than the Federal Government, even to the extent of completely banning the sale and use of a pesticide. States are thus able to respond to their individual needs and requirements associated with population distribution, watersheds, soil characteristics, cropping patterns, climate, and methods of farming. These variables significantly affect the type, quantity, and method of pesticide application which is appropriate to the crop being treated and which is consistent with public health and environmental precautions.

The pesticide industry has proposed a variety of amendments to restrict the States' powers to regulate pesticides, claiming that some States are imposing unreasonable health and safety testing requirements prior to the registration of their products.

The NWF believes that if State authority is restricted as proposed by the chemical industry, the EPA will need to expand its pesticide program enormously to specify local use regulations throughout the country in order to assure public and environmental protection from pesticide use. While insuring that all agricultural areas have an optimum level of health and safety specifications for local pesticide use may be a reasonable goal for the future, the cost and time required to establish such regulations are unreasonable under present EPA circumstances. The NWF thus believes that State authority in this regard is appropriate at this time. It is inappropriate for the pesticide industry to seek curtailment of historic State authority in this area instead of pursuing local remedies it there is objection to State standards or their implementation. Currently, the EPA sets minimum national standards with the expectation that the States will add additional restrictions where it is deemed necessary. The NWF applauds the requirements established by California and other States which specify safety tests relating to the use of pesticides under local conditions to prevent unreasonable public and environmental exposure to pesticides.

We appreciate the opportunity to present these views.

Senator LUGAR. Thank you very much.

Mr. Feldman?

STATEMENT OF JAY FELDMAN, REPRESENTING THE NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

Mr. FELDMAN. Mr. Chairman, thank you for the opportunity to be here today.[1]

Our statement today is really based on the experiences of hundreds of people who have daily and over the years expressed deep concerns about personal problems they have had with pesticides. These people stretch across the whole country, are in virtually every State of our Nation, and have in some way or another had problems. That is, they have experienced a breakdown in the pesticide regulatory program. As a result of their problems, hopefully, I can reflect their need for solutions to you.

We are taking the position here today to reauthorize FIFRA for 1 year. We do this strictly for procedural reasons, not because we like FIFRA, not because we think it's a law that is working, or that it is protecting the public, but simply because procedurally we have endorsed the House approach and the will of the Senate to move ahead and reauthorize this act.

There is a qualifier to our support in the House. We support the House bill because the House leaders have told us that they will expeditiously address legislative proposals or remedies that have been proposed.

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[1] See p. 142 for the prepared statement of Mr. Feldman.

The point and the problem certainly of S. 1263 is that a 2-year extension of this statute puts the American people and their safety on hold. Unfortunately the Congress cannot hold back the life-threatening effects on a daily basis for that 2-year period while people are on hold. And unfortunately, we don't always have the technology to clean up after that 2-year lapse and repair a life that has been destroyed by a pesticide contamination incident.

So what we are faced with, Mr. Chairman, is the fact that communities that have had ground water contamination don't want to wait. They don't want to be put on hold for 2 years. Neither do communities whose towns have been sprayed with herbicides that once drifted through Vietnam. And neither do people who consume beef and fish that have been found to have high levels of dioxin. Neither do homeowners across the country whose houses are contaminated with pesticides they thought they were using safely to treat their homes for termites. And neither do farmers or farmworkers who go to bed sick at night and endure chronic health problems. And neither do newborn or unborn children whose exposure to contaminants jeopardize their future health.

So let's get about the business, please, of looking into some of the problems that we are seeing. The numbers add up; the people add up. And the problems are not new and they are not going away.

The only difference is, Mr. Chairman, since we were here last year, there are more and more of the same problems. You can help us in leading the charge, sir, to set a course. We are not asking you to endorse any one approach or the other; we are asking you to set a course in which Congress responsibly looks at some of the problems that have been identified, that are on the table, some of the problems I have just mentioned.

S. 1263 does not do this. Voting this bill out of the Senate Agriculture Committee is like telling the American people that there are more important things to worry about than the contamination of their communities and the poisoning of their families. Some on Capitol Hill have told us that running for reelection is more important than seeking solutions to the problems because they are controversial. We don't believe this to be the general view.

It is our view that the American public wants to see Congress strengthen FIFRA's public and environmental protections. If that is the case, then who is pushing this other view? Who is pushing this 2-year authorization?

Well, all indications point to the chemical industry. In fact, I'm sure you will hear today, as we have heard in the House, that 2-year reauthorization is fine. No reauthorization of FIFRA and a simple 1-year reauthorization is really the same when we look at it, Mr. Chairman, because for the victim, for the person who has experienced problems with pesticides, for those who realize that the law is now working, without a reauthorization of this bill, without any reauthorization at all—that is, we adjourn this hearing and do nothing for the rest of this hearing—EPA's program won't shut down, the Scientific Advisory Panel [SAP] won't go away.

The SAP members can be retained as consultants. EPA can continue to operate as it is operating today under an appropriations bill—or on a continuing resolution—and has operated since fiscal year 1982.

So the point is, if we are going to seriously look at some of the problems that people have spoken about today and to this committee last year, then let's, for God's sake, look at a 1-year reauthorization and some of the proposals on the table. One of the proposals is called the national pesticide hazard prevention bill. And one of its sponsors, Mr. Harkin, plans to introduce this measure in the House. There are others, and there is a coalition forming in the Senate spearheaded by Senator Proxmire, who has groundwater contamination in his own State. And again a measure similar to this may be introduced in the Senate as well. This is a useful document to look at and to consider in an expeditious and sensible manner.

I won't go through the provisions of the proposed legislation right now. It is essentially a piece of legislation that tries to tighten up some of the problems we are seeing with loose registration, back door registration, emergency registration, that Mr. Johnson himself pointed to as a problem in his program.

The problem is, Mr. Chairman, that ignoring the signals that we see on a daily basis, ignoring the case that Maureen Hinkle mentioned, only costs our Nation more later. Just as EPA shut down its pesticide incident monitoring system, which tracks the rate of poisonings and other pesticide-related problems, California announced—and California is the only State with a mandatory pesticide reporting system—that the State had seen in 1982 a 27-percent increase in the number of poisonings and a 78-percent increase in the number of days poison victims were hospitalized.

Meanwhile, we are seeing staff reductions at EPA, which makes the staff unable to review adequately the data that they are assembling and receiving from industry on a daily basis. We see missing data; we see faulty data. I didn't see Mr. Johnson dwell on the missing data to a great extent in terms of the types of data actually not in the files at EPA.

What are we actually looking at? We are talking about between 79 and 84 percent of the pesticide products on the market today not having been adequately tested for cancer. That's a scandal. And that was raised in the House. Between 90 and 93 percent not having been tested for genetic damage capability. Between 60 and 70 percent have not been adequately tested for birth defects.

This is not something which we can just sit back for 2 years and wait and push and hope that EPA moves ahead on.

Now, one thing I want to end on—I did want to address the question of efficacy because it is a major question; and Mr. Sarbanes raises a major question in the sense that EPA is in the process right now of proposing new guidelines which do away altogether for all intents and purposes, with efficacy test requirements.

The EPA has proposed to waive efficacy data for all uses of pesticides except those where control cannot reasonably be observed or determined by the user and lack of control is a clear adverse health effect. Very vague guidelines.

The point is, efficacy is an integral part of the registration program. And to do without efficacy data is to ignore the fact that you have got a 1979 report that shows that most of the products passed by companies failed when tested by EPA for registration purposes. They failed the efficacy requirements of EPA.

Now, the point is, Mr. Chairman, we can capsulize this whole thing by looking at one chemical—and bear with me for 3 minutes—toxaphene. Toxaphene was suspected of exceeding risk criteria in 1977. In November 1982, over 5 years later, EPA finds without equivocation that "Toxaphene induces cancer in laboratory animals." Beyond that, there's contamination of our food products and the food chain, particularly with fish. The chemical is found to accumulate in the food chain. EPA is unequivocal about this. And then we read the suspension order or the notice of intent to cancel. EPA reveals a very complicated regulatory scheme that allows toxaphene essentially to go on being used, allows existing stocks to be exhausted, as it were, through the end of this year, 1983, and allows continued use, significant use, I might add, on soybeans, on corn, on peas. It is through 1986 that those uses continue, not to mention the fact that the uses will continue into the indefinite future for scabies treatment of beef cattle and sheep.

The reason, Mr. Chairman, that EPA is allowing the manufacturer to exhaust its supplies is that they have judged this to be, and I quote, "The most desirable means of achieving disposal of those stocks." The point here, Mr. Chairman, is that EPA really has no satisfactory solution to a problem it has finally identified after 5 years. The Agency has merely identified the most desirable solution.

EPA's own staff has said that there is so much existing stock, several million pounds, that toxic waste dumps across the country, would be unable to adequately dispose of the problem safely.

The point is we need a preventive approach. That is why we are focusing so hard on the registration program before products get on line. You will hear later today testimony from Dr. Davies, who after going through a series of discussions about the health problems, gets to his final point and looks toward the future. And he says, greater emphasis needs to be placed on cleanup of pesticides and toxic waste dumps and the need to improve monitoring of toxic pesticides in man and his environment.

I say this is the wrong approach. This committee is charged with preventing problems, with reviewing chemicals before they get on market, and as soon as that product is shown to be dangerous, pulled off the market. Therefore; we urge this committee to review expeditiously some of the concepts that we have raised here today, and that have been raised in the House, and move forward with the 1-year reauthorization of this act.

Thank you.

Senator LUGAR. Thank you very much, Mr. Feldman.

[The following material was subsequently received by the commitee:]

NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES,
Washington, D.C., August 1, 1983.

Hon. RICHARD G. LUGAR,
Chairman, Subcommittee on Agricultural Research and General Legislation, Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, Washington, D.C.

DEAR SENATOR LUGAR: We appreciate the opportunity to respond to the questions you have sent us as a follow-up to our testimony on S. 1263, a bill to reauthorize the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Question 1. EPA has been criticized for its use of emergency exemptions under Section 18 of FIFRA and for its use of special local needs exemptions under Section 24 of FIFRA. How should EPA define these exemptions to meet the Congressional intent of these sections of FIFRA?

Answer 1. The criticism of EPA's implementation of FIFRA's Section 18 emergency exemption and Section 24(c) special local needs (SLN) exemptions is based, as you know, on the huge increase and overuse of these provisions of law. As we cited in our testimony, the issuance of emergency exemptions under the "specific," "crisis," and "other" categories rose from 149 in fiscal year 1978 to 673 in fiscal year 1982, a 352 percent increase. From fiscal year 1976 to fiscal year 1982 the number of SLN registrations issued jumped 1,216 on an annual basis, from 440 to 1,656.

It has become clear that the Section 18 and 24 provisions of FIFRA are being misused as a way to avoid or circumvent Section 3 registrations. A study released July 27, 1983 by the Rural Advancement Fund of the National Sharecroppers Fund outlines the dramatic nature of the SLN problem. I have attached a copy of their report which I ask be introduced into the hearing record.[1]

Using a sample of 2,089 special local need registrations for 25 states (79 percent of all SLNs granted in 1981-82), RAF/NSF found that *90 percent of the SLN registrations are obtained by chemical manufacturers. Five companies received 46 percent of all SLNs in 1981-82.*

One way to avoid this situation is to forbid chemical companies, government institutions, such as USDA and state departments of agriculture, from applying for SLN's. Only users and their organizations should be able to request SLNs based on extraordinary local need.

RAF/NSF also found that more *than 40 percent of all SLN pesticides registered in the past two years contain chemicals registered on the basis of invalid or fraudulent tests conducted by Industrial Bio-Test Laboratories, Inc. (IBT).* For example, IBT conducted the safety tests for the three most widely used SLN pesticides (Furadan, Sencor, and Paraquat). These products received a total of 361 SLNs in 25 states in 1981-82.

Moreover, SLN permits are being issued for uses that are not, in fact, local in nature. The pest problems often being attacked are actually regional or national in scope. RAF/NSF found that *a majority of SLN registrations were issued for major crops use over a wide geographic area.* More than 60 percent of all SLNs were issued for use on 10 major crops.

For example, 97 SLNs were obtained to control nematodes on soybeans in 14 states. In 9 states, SLNs were obtained for control of broadleaf weed sicklepod. According to the report, "Mosquitoes are not a local problem. Yet 25 SLN registrations were approved in 10 states for mosquito control. Flies around livestock are another general problem. But state authorities granted and the EPA approved 184 exemptions to control flies on livestock and premises in 24 of the states studied." (*A Report on "Special Local Need" Pesticide Registrations, Section 24(c) of FIFRA,* Allen Spalt, Rural Advancement Fund, 1983, page 5.)

In a March 16, 1983 letter to Congressman Dan Glickman, the former Assistant Administrator for Pesticides and Toxic Substances, John Todhunter, said, "We agree with your constituents that there are some cases in which a significant pattern of identical SLN registrations suggests that federal registration would be more appropriate." At this point, I ask that you introduce in the record the correspondence with the group that raised this issue in Kansas, Kansans for Safe Pest Control.[2]

In his letter to Congressman Glickman, Dr. Todhunter continued, "It is likely that we will evaluate "significant patterns" of identical SLN registrations on a case-by-case basis, rather than assigning an arbitrary number of state registrations as the basis for an EPA response." However, from our point of view the problem needs a much broader response to ensure the protection of public health and environmental quality.

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[1] The study has been retained in the committee files.

[2] Retained in committee files.

It appears that EPA does not have actual information on the process a state goes through to determine that a "special local need" really exists. EPA appears to simply "rubber stamp" SLNs and not investigate whether the uses are truly local in nature or whether the public is protected from unreasonable adverse effects.

In general, we propose to eliminate from Sections 18 and 24(c) eligibility those pesticides which have incomplete data packages supoorting their registration (faulty or missing data which would be needed to support a new product registration).

We propose to amend Section 18 to read as follows:

"SEC. 18. EXEMPTION OF FEDERAL OR STATE AGENCIES.

"(a) REQUESTS.—A Federal or State agency may request (on behalf of pesticide users or their organizations) the Administrator to exempt the agency from any provision of this Act in accordance with this section.

"(b) EXEMPTIONS.—

"(1) Except as provided in paragraph (2), the Administrator may grant a requested exemption if the Administrator determines that the exemption is necessary to prevent or mitigate an imminent and substantial danger to public health or welfare.

"(2) The Administrator may not grant an exemption which would permit the sale or distribution of a pesticide for a use for which it is not registered under this Act if—

"(A) another pesticide is registered under this Act for the use, unless the applicant for the emergency exemption demonstrates that the registered pesticide is ineffective for the purposes covered by the exemption;

"(B) the Administrator determines that there is another pest control practice which could be used for the same purpose and would produce a less detrimental effect on the public health, welfare, or environment.

"(c) LENGTH AND RENEWAL.—An exemption under this section may not be issued for more than one year or renewed more than twice consequently, unless the Administrator has received an application for registration under Section 3 of this Act covering the use of the pesticide for which the emergency exemption is sought.

"(d) CONSULTATION.—In determining whether to grant an exemption under this Section, the Administrator shall, upon request, consult with appropriate state or federal officials.

"(e) PUBLIC COMMENT.—Unless the Administrator determines it is necessary to grant an exemption under this Section within sixty days of the request for the exemption, the Administrator shall publish notice of the application for an emergency exemption in the Federal Register and, in making a determination on the application, consider any information provided to the Administrator by a member of the public.

"(f) DISCLOSURE OF INFORMATION CONTAINED IN EMERGENCY EXEMPTION APPLICATIONS.—All information submitted to the Administrator in support of an application for an emergency exemption shall be disclosed by the Administrator to any member of the public within 30 days of receipt of a request for such information.

"(g) PRIOR APPROVAL OF THE ADMINISTRATOR.—In no case may this Section permit an unregistered use of a pesticide without the prior approval of the Administrator: Provided, That the Administrator must act upon an application for an emergency exemption within 48 hours if he concurs with the applicant that extraordinary emergency circumstances exist where immediate pest control measures are necessary to prevent imminent and substantial harm to man, the environment, or the public welfare."

We propose to amend Section 24(2) to read as follows:

"SEC. 24. AUTHORITY OF STATES

Section 24(c) is amended—

(1) by striking out "federally registered pesticides" in the first sentence of paragraph (1) and inserting in lieu thereof "Pesticides which are registered under paragraph (5) or (7) of Section 3(c) and";

(2) in paragraph (2)—

(A) by striking out "for more than ninety days if disapproved by the Administrator within that period" in the first sentence and inserting in lieu thereof "until ninety days have elapsed after the date on which the Administrator is notified by a state of the intent of the state to issue the registration";

(B) by inserting after the first sentence the following new sentence: "If the Administrator disapproves the registration during the ninety day period, the registration shall not become effective."; and

(C) by striking out "(A) on the basis of lack of essentiality of a pesticide or (B)" in the last sentence;

(3) in paragraph (3)—

(A) by striking out "or" in the second sentence and inserting in lieu thereof "that";

(B) by inserting after "hazard," in the second sentence the following: "or that the registration is unnecessary to meet special local needs and therefore the registrant should apply for registration under Section 3(c)(5),";

(C) by striking out "may" in the second sentence and inserting in lieu thereof "shall"; and

(D) by adding at the end thereof the following new sentence: "If at least five states provide under this subsection for the registration of an additional use of a pesticide to meet the same special local need, there shall be a rebuttable presumption that a special local need does not exist for purposes of this subsection.";

(4) by striking out "may" in the first sentence of paragraph (4) and inserting in lieu thereof "shall"; and

(5) by adding at the end thereof the following new paragraph:

"(5) A registration issued by a state under this subsection shall expire after a five year period. At the end of each five year period, the state may issue a new registration in accordance with this subsection.".

Question 2. What actions should be taken by EPA to fill the data gaps resulting from the IBT situation? What can be done to prevent this type of situation from occuring in the future?

Answer 2. As the Subcommittee knows, for years, EPA has been accepting faulty health and environmental test data on pesticide products now on the market. One of the largest falsifiers of data, the Industrial Bio-Test Laboratories, Inc. (IBT), provided EPA with hundreds of chemical safety tests to support the registration of nearly 200 products EPA has verified that only 3 percent of the IBT data submitted is currently valid.

A first response to this situation should be to aggressively inform the public that EPA has not determined the capacity of the chemical to cause harm to humans and the environment. The public remains uniformed and users of pesticides generally assume that EPA registration equates with full and adequate testing and evaluation. Supplementary product labels should be sent out immediately on any product registered with faulty data or whose data package is otherwise incomplete because of missing health or environmental data. We endorse the recommendation of the Natural Resources Defense Council that a consumer alert be used, such as the following:

Warning: The government licensing of this chemical was based on false, fabricated, fraudulent or invalid scientific data conerning whether it may cause cancer, birth defects, nerve damage or other chronic health effects. EPA is unable to approve this chemical as safe when used according to its instructions.

Secondly, short of a complete and justified suspension of products registered with faulty data, EPA must establish rigorous time lines and specific deadlines for data replacement. EPA, in the past has not been able to comply with deadlines of the registration program. Therefore, the time lines, if not adhered to, must be followed with a chemical product ban.

In terms of looking toward the future, we should look to others, such as Canada, for an example. Canada, faced with the same faulty data situation as the U.S. has banned or restricted 6 IBT chemicals while our country has taken no such action. In fact, EPA officials maintain that the law prohibits taking action similar to Canada without *"valid evidence of risk, as opposed to a lack of information."* As a result, products remain on the market with invalid tests supporting their registration until such time as EPA can show environmental or human harm. To the contrary, the Director of the California Department of Food and Agriculture is required to cancel a pesticide registration when "the applicant has submitted inaccurate or incomplete information." [3 Cal. Admin. code § 2360(d)]. FIFRA, too, must mandate product suspension if registration is based on faulty data.

Somehow, we must seek to eliminate the current conflict-of-interest situation created by registrants providing EPA with health and safety data to support product registration. We endorse the idea of third party testing by government approved laboratories whose standards are monitored. To do this EPA must improve its lab audit program and its follow through on identified problems.

Despite the extensive problems with lab practices and even though EPA has audited nearly 100 testing labs since it began its lab audit program in 1977, questionable lab practices continue. According to a report in the *San Jose Mercury*, March 6, 1983, "None of the most suspect labs has been audited again. And despite the questionable value of some of the studies, not one pesticide registration has been withdrawn." According to a December, 1982 report of the Subcommittee on Department Operations, Research and Foreign Agriculture, Committee on Agriculture in the U.S. House of Representatives, "Except for the IBT case (which occurred before the audit program began), there is no solid indication, however, that any decisive regulatory or enforcement actions have been taken as a result of the laboratory audit program."

Question 3. In your opinion, what can be done by EPA to accelerate the reregistration process, while assuring that the process is effective in its review of "old" chemicals?

Answer 3. Part of the problem with reregistaration is that there is little, if any, incentive for industry to assist in seeing that their products are reregistered quickly and efficiently with the best science. Products continue to be marketed with "old" registrations and missing data. All that EPA will say is that, "All registrants of like products will have to provide missing data at a time specified in the future." No specifics are forthcoming and there is no compliance with deadlines once established.

The way to get the reregistration program on track is to establish specific deadlines with product suspension if data is not forthcoming. Further, products out of compliance with the most recent registration standards should not be eligible for any one of a number of "backdoor" registrations, such as conditional, emergency and special local need registrations, until products have been fully tested according to modern safety standards.

Finally, EPA will never be able to tackle the tasks inherent in our proposals or even the existing law if the Congress does not authorize and appropriate adequate funds. Budget reductions in EPA's Office of Pesticide Programs to the tune of $20 million over the last several years has only served to further jeopardize the public's health and environmental quality.

Thanks for the opportunity to comment on these matters. We look forward to working with you in an effort to improve the protections from pesticides afforded the public.

Sincerely,

JAY FELDMAN, *National Coordinator.*

Senator LUGAR. Ms. Warren?

STATEMENT OF JACQUELINE WARREN, REPRESENTING THE NATURAL RESOURCES DEFENSE COUNCIL

Ms. **WARREN**. Thank you very much, Mr. Chairman.

I am presenting my testimony not just for the Natural Resources Defense Council but for a coalition of 16 environmental labor and consumer organizations, and I have the support of those other organizations that are not represented to testify for themselves.[1]

I have been working as an attorney on pesticide regulatory problems for the past 10 years and have lived through some of the various iterations that FIFRA has gone through. I must say that listening to Ed Johnson talk, and his statement about how successful the program has been, it's a bit like Alice in Wonderland for me. Anyone who's read the newspapers over the last year cannot but be aware of the fact that wells have been closed by the thousands on Long Island because of pesticide contamination. DBCP has been found in ground water in California. Detection of pesticides in drinking water is an emerging problem which is not dealt with by EPA's pesticide program.

While there is a concern with food tolerances, there isn't a concern with pesticide residues in drinking water.

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[1] See p. 150 for the prepared statement of Ms. Warren.

There has also been a problem with a number of banned pesticides, such as aldrin and dieldrin. Although they have been banned because of an imminent hazard to health, they were left on the market for termite control on the basis that there would not be any human exposure. Now, we are beginning to find out that many houses have been contaminated by misuse of those pesticides for termite control. This is a problem that needs to be addressed, and it needs to be addressed now.

Then there is the IBT scandal, which has been in the newspapers lately, and a whole slew of reports that have come out of the Senate Judiciary Committee, and the General Accounting Office. Now for the first time in the last 10 years, one of the authorizing committees that has FIFRA, the House Agriculture Committee, has issued an investigative report that documents serious continuing problems in the pesticide program, such as cut and paste reviews of data, and a very miniscule laboratory audit program, even in the face of the IBT scandal.

The fact that—going back to the termite control contamination problem, the fact is that an applicator walking into a person's home does not have to have demonstrated a capability of handling that pesticide himself. An application simply has to work with somebody that has a license. As I said in another hearing, I'm glad airline pilots are not licensed that way.

So having said that, from our point of view there are a number of problems in the pesticide program that are really very important. The numbers that Ed Johnson talked about for section 18 emergency exemptions and section 24(c), special local needs registration; in fact, the numbers don't tell the whole story. If you think about what they mean, they mean that pesticides that have not been approved by the section 3 registration process, as is the case with the section 18 exemptions, are being widely used, and that many compounds are being registered in up to 30 States on the basis of special local need, but are held to a much lesser standard for test data submission. Yet these become permanent registration.

We believe these exceptions should be cut back. We also need a definition of what's an emergency, so that something doesn't just become an emergency when someone who wants to use an unregistered compound has an influence on someone in the program.

These are the kinds of problems that cannot wait for solutions for another 2 years. They have been building up over many years. Some of the legislative attempts to correct these problems have been more successful than others. But in general I think that not just we, but the various investigative bodies that have looked at it, are concluding that there are problems with EPA's implementation of FIFRA that haven't been resolved and ought to be.

I also think that in spite of the Agency's statement that everything is wonderful, put off any amendments for 2 more years, there's another point of view in all fairness needs to be heard and addressed at this time.

The agricultural chemical industry has come in here every other year asking for changes, and there have been 1-year reauthorizations, with amendments. So to give us a simple 2-year authorization without considering the amendments—which I am going to give to you today just for your consideration—would be unfair. Our proposals contain several changes to FIFRA that flow from the House subcommittee's investigative report and from the GAO's reports. They also are responsive to the lack of EPA enforcement, and the fact that the pesticide program isn't protecting public health. We hope that you will give us the same consideration that has been shown in prior years to the manufacturer of pesticides, in considering the problems of ground water contamination and home contamination and the other matters we address. These are problems that are not going to go away, and you are going to be hearing more about them.

There already seems to me to be a growing and greater awareness in the general population about the problem of pesticide contamination than there has been in the past. I don't think that that's going to go away, either.

I'd like to speak to some other specific issues in addition to the ones that I have already mentioned. The real heart of the pesticide law is the reregistration program, because many pesticides were on the market by the time of the major FIFRA amendments in 1972. These were to be reregistered by EPA on a 5-year deadline, and held up to new pesticide registration standards. As EPA tried to do this, it became clear that 5 years was unreasonable. Therefore the deadline was simply eliminated. We feel that a new deadline should be put back in the law.

Ed Johnson says that a chemical can be reregistered as soon as chronic testing is begun, I don't think a pesticide ought to be reregistered until the data are in and screened to see whether the chemical meets the standards for registration. To simply chalk up numbers of pesticides registered seems to me to be misleading. If you look, as the House subcommittee did, at how the Agency got rid of its reregistration backlogs, what you are going to see is a new set of cancer risk evaluations. Pesticides that were considered carcinogenic last year aren't this year. You will also see a kind of quick processing, and cut and paste reviews which are documented in the report and which consist of cutting out the registrant's conclusion about a study and calling it reviewed. That it doesn't suffice for the kind of review that the reregistration program embodied in section 3 of FIFRA really intended.

That's one of the major problems.

The idea that 95 percent of the pesticides in use, which Ed Johnson said just before, will be under test at some time in the near future, is also very disconcerting to me. People want to know and believe that pesticides that are in use, and that are going to show up in the food chain, are safe if they are there. The fact that those are all just now going under test is not grounds for applause for the success of the program. I think it's grounds for concern and for the placement in the pesticide law of a provision that says if these studies aren't finished within 3 years—I don't think any study should take longer than 3 years—that registration is canceled. After all, this has been going on now since 1972. For the past 10 years, the registrations are supposed to have been reviewed.

By the same token, the idea that only 89 of the 600 basic active ingredients really warrant special review just sounds suspicious to me on its face in light of the fact that 62 percent, or some large percent, according to the House report, have not been subjected to carcinogenicity testing. How can one say that only 89 of 600 warrant special pesticide review when there are so few studies for so many of them? That is one of the key issues that we would like to see addressed.

We have also dealt with a number of other issues in our suggested changes. One has to do with the impact of the Grassley-Allen amendment on the pesticide program in a procedural way. A number of events have had the overall result that the public is effectively precluded from participation in the pesticide review process.

Originally when a question of safety arose regarding a pesticide, it was to be decided at an open public hearing, with benefits and risks openly considered. That has now evolved into a decisionmaking procedure where EPA sits down with the regulated industry to see if there are validated studies that might prompt a special review. The public is completely out of the process. We don't know what it is that a particular registrant says to EPA behind closed doors in persuading them against having a public review. Nobody is any the wiser. We would like that process opened up if that's what Grassley-Allen really means. If that is what it means, we think it ought to be repealed.

We would like to see environmental and labor groups again have standing to challenge pesticide regulatory decisions in agency hearings. As it is now, the initial notice of EPA decision comes out and there's a comment period, although certain data aren't publicly available because of the disclosure restrictions. After EPA makes its final determination, if the industry is unhappy with what's happened, they have a right to a hearing at EPA to challenge the breadth of the regulatory determination.

If environmental or labor groups feel that EPA has made the wrong determination, that the Agency overlooked some evidence or didn't go far enough, they don't have the right to ask for a hearing. This is because about 3 years ago, EPA interpreted the words in FIFRA section 6 "a person adversely affected" to mean that only people with an economic interest in the continued use of the pesticide, not those concerned about the health and safety effects of the pesticide's use, can be adversely affected by a pesticide regulatory decision.

We would like to see that provision changed back to the way it was before, and would like that done in this session of the Congress. We would like to see a private right of action put into the statute. EPA's enforcement capability has been greatly diminished. Their staff has been cut by a third in the pesticide program.

Many of the statutes provide for citizen enforcement of statutory violations, and we think it would be appropriate in this situation to enable them to protect themselves against injuries as a result of a violation of FIFRA by having the statutory right to sue.

There are other provisions which I don't want to take any more time with, but I would like to submit for the record a copy of the so-called Harpers Ferry bill,[1] which contains the recommendations of a large group of environmental, labor and consumer organizations who sat down with the pesticide law and went through it, and every place we saw the kinds of problems involved in the last 10 years, suggested a way it might be changed to open up the process.

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[1] A summary of the Harpers Ferry bill will be found on p. 167; the entire bill was not reprinted because of cost considerations and was retained in the committee files.

So I would like to ask that it be put in the record.

Senator **Lugar**. Without objection, that will be included in the record.

Ms. **Warren**. I'd just like to conclude by saying that very serious public health and environmental issues have been raised in the testimony that these witnesses have presented and in the various investigative reports that I have referred to. The Senate doesn't need 2 more years to find out what the problems are. We know what the problems are. And I think it really would be appropriate to get on with it now and begin to look at them.

What the House has done is to pass a 1-year reauthorization and has promised to get on expeditiously with consideration of changes to FIFRA. That's really all we are asking for, and we would like to get the same fair shake from the Senate.

Thank you.

Senator **Lugar**. Thank you very much.

Let me offer the suggestion that in the course of legislation that certainly that consideration will be given.

Those of you who attended the hearings on the markup in this area last year would recognize there are differences of viewpoint. And the limited bill that came through reflected that.

I have no way of predicting where other forces lie this particular year or what the will of the committee will be quite apart from that of the Senate as a whole. But the Agriculture Committee was eager and willing to deal with these issues and will, too, I suspect, again this year. And we appreciate very much this time and the input today. And I think your testimony comes through loud and clear, vividly and collectively. We appreciate your coming.

The Chair would like to now call the next panel of Jack Early, National Agricultural Chemicals Association; Ralph Engel, Chemical Specialties Manufacturers Association; and Dennis Burchette, Pesticide Producers Association.

Good morning.

The Chair would like to introduce a statement by Senator Huddleston to be put in the record.[1]

Gentlemen, would you please testify in the order that I introduced you.

Mr. Early.

STATEMENT OF JACK EARLY, REPRESENTING THE NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

Mr. **Early**. Thank you, Mr. Chairman.

The National Agricultural Chemicals Association is a nonprofit, trade organization of manufacturers and formulators of pest control products employed in agricultural production. Our membership is composed of the companies which produce and sell virtually all of the technical crop protection materials, active ingredients, and a large percentage of the formulated products registered for use in the United States.

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[1] See p. 73 for the prepared statement of Senator Huddleston.

Mr. Chairman, last year you and the members of the Agriculture Committee reported a bill to amend FIFRA. A major part of that legislation addressed problems with the existing law concerning proprietary protection for research data.

The proposed changes to section 3 of FIFRA were intended to insure that there would be strong incentives for companies to engage in costly and risky agricultural research and development. The proposed restructuring of section 10 of FIFRA was intended to prevent the disclosure of valuable research data to competing pesticide producers. These amendments were passed by the House of Representatives and reported by the Senate Agriculture Committee, but have not yet been enacted into law.

The problems that gave rise to this bill have not disappeared, Mr. Chairman. FIFRA places an enormous and growing regulatory burden on innovators. It has been our industry's experience that unless FIFRA is changed to remedy the imbalance between the great regulatory burdens FIFRA places on innovators, and the virtually free ride FIFRA gives to imitators, the incentives for innovative agricultural research will continue to decline along with our technological base.

These problems cannot be cured through administrative action. They require a restructuring of FIFRA itself and this can only be done by Congress.

On April 19 of this year, a U.S. district court handed down a final decision in the case of *Monsanto* v. *EPA*. The decision recognized that innovative companies have a proprietary right, protected by the Constitution, to prevent competitors from gaining access to, or using, their research data. It enjoined the operation of those parts of sections 3 and 10 of FIFRA that give imitators a free ride on the efforts of innovators. We understand that EPA plans to appeal this ruling to the Supreme Court.

While the *Monsanto* case is on appeal, we feel it would not be appropriate for Congress to enact amendments to FIFRA. We think it would be prudent to wait until the Supreme Court has considered the constitutionality of the existing law before Congress attempts to change it.

Nevertheless, whichever way the Supreme Court rules, it will not alter the fact that a strengthening of FIFRA's protections for proprietary research will ultimately be needed. Research and technology can only prosper if the fruits of the innovator's efforts are protected from exploitation by others. The current FIFRA does not achieve this objective.

Although fundamental changes in FIFRA will be necessary, we recognize that in the meantime there is also an urgent need to authorize appropriations for FIFRA and to reauthorize the FIFRA Scientific Advisory Panel.

The new EPA Administrator should be given an opportunity to familiarize himself with the program so that he will be able to appreciate why these changes are needed. For these reasons, we support the reauthorization of FIFRA for 2 years and the reauthorization of the SAP for 5 years.

Our industry has a serious commitment to agricultural research. Agricultural research has enabled us to feed our country and much of the world, and contributes tens of billions of dollars each year to our national economy.

We know that this committee appreciates the need to preserve strong incentives for research and has tried to enact appropriate legislation to accomplish this. We will continue to seek the legislative amendments to FIFRA that we believe are needed and ask for your continued future assistance in this effort.

Mr. Chairman, we appreciate the opportunity to present our views. We would be pleased to respond to any questions you and the committee might have.

Thank you.

Senator LUGAR. Thank you very much, Mr. Early.

[Written questions from Senator Lugar and Mr. Early's responses thereto:]

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Washington, D.C., July 20, 1983.

Hon. RICHARD G. LUGAR,
Washington, D.C.

DEAR SENATOR LUGAR: The purpose of this letter is to respond to the two enclosed questions which we received from your office recently regarding ground water and the IBT situation.

Question 1. What actions are being taken by the chemical industry to investigate ground water contamination? How is the industry preparing to moderate the possibility of any contamination in the future?

Answer 1. Ground water.—

(A) Industry, by company separately or through association efforts, is working with state and federal agencies to develop monitoring systems, implement chemical standards, improve chemical detection procedures and communicate concerns for soil and water management to those segments impacted by agricultural uses of agrichemicals. Actions taken are:

(1) NACA position paper and programs (copy enclosed).[1]

(2) Chemical Manufacturers Association position and programs.

(3) Wisconsin legislative initiative supported by industry participation.

(4) Florida concerns that are being addressed by industry.

(5) NACA and EPA joint working activities to address chemical standards for health effects evaluation.

(6) NACA testimony to Science Advisory Board on health advisory levels.

(7) Public statements by NACA calling attention to possible problems: Associated industries; farming community; proper label use; remedies for accidental spillage etc.; soil and water conservation.

(B) Future water contamination problems can be moderated by:

(1) Alerting farmers of potential problems—awareness of preventative measures.

(2) Promotion of soil and water management practices: Conservation tillage; reduce soil and water erosion; manage tailwaters more efficiently; control irrigation to needs only; soil type identifications product use rate and method of application; managing recharge wells.

(3) Expanded laboratory testing identifying chemical leaching and biodegradation characteristics.

(4) Cooperative evaluation and scientific development of computer modeling techniques with academic and federal agencies.

(5) Development of scientifically sound health advisory levels that encompass the broad base of potential soil and water contaminants.

Question 2. How has the chemical industry responded to the IBT situation? What is the extent of the industry's cooperation with EPA in completing the data base which has been effected by IBT data? What action has the chemical industry taken to avoid a similar situation in the future? Is it possible to estimate an economic loss to the chemical industry resulting from the IBT situation?

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[1] The NACA position paper has been retained in the committee files.

Answer 2. *IBT.*—The EPA report issued on July 11, 1983 gives a fairly complete update on industry response to replacement of IBT studies to support product registration. The industry cooperation with EPA has been excellent in face of the fact that agency validation of studies and response regarding agency positions has been slow. Based on the EPA report, only five products of minor use are supported only by IBT data. The over 200 products supported by IBT data have had most if not all IBT data validated, replaced, underway or are still under discussion with EPA.

Industry action to avoid similar situations is positive. Company monitoring, indemnity, good laboratory practice (GLP), EPA and FDA laboratory inspection, better qualified toxicologists and physical facilities, and improved quality assurance are some of the things that industry is supporting and implementing to avoid a similar experience in future years.

It is estimated that losses to the industry may approach levels from 500 million to 1 billion dollars. This is in (1) cost of validation, (2) cost of redoing the studies, (3) loss of registrations, (4) delays in getting products to the market place, (5) the adverse impact on international registrations and market participation, (6) loss of patent life due to registration delays, and (7) loss of credibility and the impact of bad press on the public and the stock market. When the long-term effects are calculated, the total combined loss to the industry could even be higher.

The EPA report on IBT is enclosed.[1] A press conference was held and a press release was circulated by EPA providing a wrap up of the IBT situation. Of the 35 products quoted in the press that faced suspension unless data were generated, only 19 were actually listed as facing suspension in the enclosed categorical breakdown by EPA. These 19 represent products of minor market significance and many may eventually be removed from the market because the economic potential does not justify further data generations for reregistration.

Sincerely,

JACK D. EARLY.

Senator LUGAR. Mr. Engel.

STATEMENT OF RALPH ENGEL, REPRESENTING THE CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

Mr. ENGEL. Thank you, Mr. Chairman.[2]

CSMA, as you recall, has a membership of nearly 400 firms engaged in the manufacture, formulation, distribution and sale of insecticides, disinfectants and sanitizers, detergents and cleaning compounds and a number of other household products as well as for industrial and institutional uses. A significant number of these products have pesticidal claims and are therefore subject to EPA jurisdiction, pursuant to the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

Specifically, you recall CSMA represents the nonagricultural pesticide industry. And although we support S. 1263 and its 2-year reauthorization, we would like to take this opportunity to briefly discuss some of the concerns that we have with the existing statutes.

CSMA has in the past expressed serious concern over the development and implementation of guidelines which were intended by Congress to set forth the kinds of data which would be required to support a registration. The congressional intent behind section 3(c)(2) of FIFRA is to specify generally the kinds of basic data or information which may be required to support a registration, but at the same time permit latitude and flexibility on the part of scientists in developing their data.

During the 97th Congress, CSMA worked with EPA, Members of Congress, and other interested parties to achieve some legislative changes to FIFRA, section 3, to correct the guidelines problems. Since there was no further action, this was not enacted.

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[1] The EPA report has been retained in the committee files.

[2] See p. 183 for the prepared statement of Mr. Engel.

While EPA has moved a long way in addressing this problem, we believe that the FIFRA statute should appropriately address this issue so as to reflect congressional intent similar to that expressed in H.R. 5203 during the last Congress. Congress added a new requirement to FIFRA in 1978 to the effect that regulations prescribed by the Administrator to carry out the act must take into account the differences in environmental risk and the appropriate data for evaluating such risk as between Ag and non-Ag pesticides.

We specifically urge this subcommittee to provide specific language directing EPA to separate out and utilize current administrative staff to specifically administer any regulations and guidelines which pertain to the non-Ag portion of the pesticide industry. It is made up of small volumes, Mr. Chairman. But we probably represent two-thirds of the registrations at EPA.

The administration is promoting the establishment of user fees whereby the beneficiaries of governmental programs pay for these services in a direct way; namely, industry. A Federal user fee for pesticide registrations is not desirable due to its impact on development costs, particularly for small businesses, and its effect of inhibiting the registration of new or improved products.

Our objections are sixfold: First, user fees would be unfair because EPA benefits the general public, not just those who produce products; second, if user fees pay for most of the agency's expenses, there is no real cost constraint on these regulatory operations. Third, a system of pesticide registrations would dramatically increase product development costs and have an unfair and disproportionate impact on small businesses.

Fourth, imposition of registration fees at the Federal level would add to the considerable number of similar expenditures already required at the State level. Fifth, due to the preclearance marketing procedures in the registration process, it would be inequitable to charge pesticide producers for the cost of a program which inhibits their ability to market their products. Sixth, a user fee has been frequently interpreted to be a tax or a revenue-raising measure and consequently could give rise to a jurisdictional concern. We believe that the program is ill advised and we therefore urge the subcommittee to reject it should it be forthcoming.

In our last testimony before this subcommittee, we called your attention to inconsistencies in labeling requirements generally caused by product managers recommending or requiring a label format contrary or in addition to existing labeling regulations. We are pleased to advise that the Agency will be incorporating label changes and amendments to section 3 registration regulations to be proposed sometime in the near future. We nevertheless still find a few States intruding in this area from time to time.

Section 24(b) of FIFRA specifically prohibits States from requiring labeling in addition to or different from that of the EPA. We believe that additional support from Congress is needed to reinforce congressional intent of State preemption to avoid conflicting requirements in the various States. This reinforcement can be accomplished by restating the preemption language of section 24(b) in the subcommittee report.

Mr. Chairman, some have criticized industry testing across the board and suggested that in addition to its own review, the EPA should require that independent or Government laboratories review all data submitted under FIFRA. We believe this suggestion is quite inappropriate and we respectfully urge the subcommittee to reject this approach.

Industry laboratories are among the very best in the world have some of the best scientific facilities and most highly acclaimed research scientists. The overall record indicates the industry has done an excellent job of testing and has established the highest quality of research. In fact, the science of toxicology has come from industry itself.

As a result, impressive progress is being made in achieving a sound data base on the health and environmental effects of existing chemicals.

During the 97th Congress, the Senate Committee on Agriculture, Nutrition, and Forestry worked long and hard on the proposed changes in section 24(a) dealing with State authority. I want to tell you how much we at CSMA appreciated your concerns and efforts to amend this section. Needless to say, the discussions over section 24(a) were frequently misunderstood or misconstrued.

Although several of these same problems with section 24(a) still exist today, we would like now to focus on only one segment of section 24(a) dealing with whether or not political subdivisions of the State, such as a county or township, should be able to exercise the same pesticide jurisdiction as a State. This problem exists today and threatens to spread to other political subdivisions, having little, if any, understanding of the structure of the pesticide industry or ramifications of the attempted regulations.

We believe that the statute ought to reflect a congressional intent that political subdivisions below the State level should not regulate the sale or use of pesticides. Senator Sarbanes has introduced a bill titled S. 780, a bill to require that EPA maintain a facility for the biological testing of pesticides under FIFRA. And it's specifically directed at disinfectant materials. It is not related to the IBT incident. I call that to your attention, and for the record as well.

We believe it is appropriate to have one Federal laboratory facility that has the authority to provide testing of disinfectant materials and thus avoid conflicts over testing methods and test results. We agree with the Senator. Without such a laboratory, we foresee the possibility of 5, 20 or even 50 States obtaining varying test results in a very rigorous test that's required for disinfectant testing on the same product, and thereby taking different enforcement actions. Even with only three States currently conducting the tests, namely, Florida, North Carolina, and Virginia, there is early evidence of differing test results between them, on the same product.

Multiply that example by hundreds of products, and you can see the potential confusion that would result. Now, if we extend that scenario to a point where an enforcement action in one State is being challenged, we can envision contradictory data from other State testing labs being presented in opposition to the data from that one State.

Since its inception, the House and Senate committees dealing with agricultural matters have exercised their legislative jurisdiction over FIFRA, and we hope this legislative legacy is continued. FIFRA, however, was not reauthorized in either 1981 or 1982 by the Congress. The passage of a continuing resolution kept the pesticide registration program at EPA properly funded.

We would respectfully urge the subcommittee to reauthorize FIFRA for 2 years, and thus refute any possible jurisdictional claims.

In addition, the Scientific Advisory Panel had a sunset deadline of September 30, 1981, and has run out of legislative authority. It also needs to be reauthorized so that proper scientific peer review can again be utilized to comment on pesticide matters.

Consequently, we would respectfully urge that the subcommittee consider at this time only a simple reauthorization for 2 years, with a new SAP for 5 years.

We fully support S. 1263. We believe it will be most appropriate for the new EPA Administrator to have sufficient time to review the Agency's priorities and to review FIFRA and the pesticide programs. Although we have commented on several problems inherent in the existing FIFRA statute, we suggest the subcommittee take up these matters at a future time, certainly after the Supreme Court has considered the constitutionality of the existing law under the *Monsanto* case. To do otherwise would mean sitting here writing language that could be meaningless.

Many of the concerns we have discussed today impose an economic burden upon our industry and deprive consumers of safe and effective pesticides needed to control pests which disrupt our economy and reduce the quality of our lives. The CSMA is committed to work with this subcommittee to resolve these important problems at the appropriate time.

Thank you, Mr. Chairman, for the time to comment. And we are prepared to answer any questions you might have.

Senator LUGAR. Thank you very much, Mr. Engel.

Mr. Burchett.

Mr. MILLER. Mr. Chairman, my name is George Miller. I am substituting for Dennis Burchett.[1]

Senator LUGAR. Welcome.

STATEMENT OF GEORGE MILLER, REPRESENTING THE PESTICIDE PRODUCERS ASSOCIATION

Mr. MILLER. Thank you.

We represent the smaller producers and formulators and I would like to thank you for this opportunity to be able to testify before you today. I am just going to make a summary of our main points and then talk about a problem that is of a deep concern to the Pesticide Producers Association here today.

Though there are many problems existing in the present law, we are not going to address them all today. We don't think that you would have the time, nor ourselves. We'd rather simply talk about the reauthorization of FIFRA and the Scientific Advisory Panel.

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[1] See p. 198 for the prepared statement of Mr. Burchett.

We feel that due to a new Administrator just taking over at the Agency and other assorted Agency problems, that FIFRA be reauthorized for at least 2 years and the Scientific Advisory Panel be reauthorized for 5 years. Now comes our deep concern. This is caused by Government laws, regulations, and industry court cases which we feel are leading the agricultural chemical industry into an area of noncompetitiveness and monopoly. The small entrepreneurs can no longer succeed in the pesticide industry today. In another industry without the laws and regulations that we have in the pesticide industry, any company could manufacture an invention after the expiration of the patent. Not certain pesticides.

In our industry, a patent expires, and you still can't produce the unpatented product, not until you obtain a registration. You go to EPA to obtain that registration; you have to produce data. The cost of that production of data is more than the net worth of many of our small companies. There's no way a small company can become an independent producer today.

Legislation in this case is extending the patent and fostering a monopoly. Legislation is precluding small companies from entering into the basic manufacturing position in the pesticide industry. When we next take up FIFRA, the Pesticide Producers Association may have some answers for this problem. But at this time we are bringing the problem to your attention so we can jointly find a solution.

I would like to thank you.

Senator LUGAR. Thank you very much, Mr. Miller.

Gentlemen, all three of you have testified in favor of a 2-year extension with the 5 years for the panel and suggested that the *Monsanto* case needs to be resolved prior to moving ahead. You have heard the previous witnesses, however, bring forth a number of thoughts regarding the health and safety of Americans from pesticides.

Do you have any response to the urgency that they have requested? Essentially, I would summarize their testimony as saying 1 year of authorization simply because the form of the thing ought to be continued. But we should not perpetuate the law, as they see it, for a period longer than that. And by having a 1-year authorization, there is some urgency in the timetable of taking other issues.

Do you have a thought about that, Dr. Early?

Dr. EARLY. I do. I am sure my colleagues may also have a comment they'd like to share.

I really don't share the degree of urgency or necessarily agree with all the issues and the problems and the innuendoes you may have heard this morning. Obviously, I have some concern about some of the so-called problem areas that were raised. I don't think the problem is of the magnitude that you heard earlier this morning.

Having said that, you know, I did not hear anything this morning by some of the other witnesses that said anything new to me. I didn't hear anything new we hadn't heard before. You are aware that we went through a very controversial period for a couple of years trying to resolve some of these significant differences. It hasn't been easy; it's not going to be any easier.

We in the industry, of course, are perfectly willing to sit down and try to resolve these differences. I am concerned that we cannot resolve these differences in a very short period of time, particularly as we come into a Presidential election year next year. This controversy needs to have this committee and our industry's undivided attention for some period of time.

So I think we should go for 2 years. I think that's an appropriate period of time. In the meantime, we can certainly get on with the issues and try to resolve them. Certainly, the Administrator of EPA needs a little period of time to come up to speed. I'm not aware that pesticides are a priority issue for him. The news media appears to say that it's toxic waste and other issues.

So I think that with the Supreme Court not acting on this issue, the *Monsanto* v. *EPA* court case for 18 months or so, if it follows their normal schedule, 1 year is just going to be unrealistic. I think 2 years is a more realistic, pragmatic approach to the issue.

Senator LUGAR. Mr. Engel, do you have a thought?

Mr. ENGEL. Yes, Mr. Chairman.

I do have some concerns about what was raised here earlier by other witnesses. Although I again want to state we represent the nonagricultural area, I don't frankly think we should be put in the same category with the agricultural community per se.

We have not heard anything new that hasn't been raised before. Many of these concerns raised earlier can indeed be handled administratively by the Agency. They have the authority to deal with almost every issue I have heard raised. If there is a misuse, or abuse under the act, it can be handled without having new legislation.

Let me raise another point which concerns me. We were involved over the last 2 years in attempting to get some legislation written as you are very well aware. During that whole time, I found that my colleagues on the last panel used the tactic to delay all the way through the process until the 97th Congress went out of existence. They didn't push the points they raised at this table today, but delayed instead. Consequently, I don't necessarily listen to that language with the greatest of urgency that perhaps they are raising about the 1-year cycle.

Last, 2 years in the legislative cycle is not exactly 2 years as we normally perceive it. If we reauthorize for 1 year, we will be back here in a few months and start the process all over again. If we authorize for 2 years, we will come closer to make it 1 full year. Those are my only comments.

Senator LUGAR. Do you have anything further——

Mr. MILLER. Mr. Chairman, basically I'm in the industry, though I am here on behalf of a trade association. I really want EPA to hear this, but in certain areas, especially the data call-in area, I think they are doing an exceedingly fine job. I know I am in four task forces now trying to produce data to support registration.

I can only say other than that that Rome wasn't built in a day. And we are trying to build it in a day; whereas, in the past, we had different law, and if you talk about toxics, you talk about dumping, we were allowed to do things that are not permitted today.

Therefore, I think the Agency is trying to do their job as mandated under FIFRA. And 2 years is fine.

Senator LUGAR. Gentlemen, we thank you very much for coming this morning and for your testimony.

The Chair would like to call now a panel composed of Bruce Hawley, American Farm Bureau Federation; Dr. John E. Davies, chairman, department of epidemiology and public health, University of Miami School of Medicine; Dr. Dewayne Torgeson, program director of bioregulant chemicals, Boyce Thompson Institute for Plant Research, Cornell University, Ithaca, N.Y.

Welcome, gentlemen.

Would you please testify in the order that I introduced you. And that would mean first of all, Mr. Hawley.

STATEMENT OF BRUCE HAWLEY, ASSISTANT DIRECTOR, WASHINGTON OFFICE, AMERICAN FARM BUREAU FEDERATION

Mr. HAWLEY. Good morning, Senator Lugar. Thank you.

My name is Bruce Hawley. I am the assistant director of the Washington office of the American Farm Bureau Federation.

The American Farm Bureau is a general farm organization in 48 States and Puerto Rico. Farm Bureau membership produces virtually every crop grown in commercial quantities in the United States. Farm Bureau membership accounts for over 75 percent of all agricultural pesticide usage. Scientifically sound regulation of pesticides is critical to agriculture's ability to sustain today's unprecedented levels of production. We call on this committee to report a 2-year reauthorization of FIFRA, and the Scientific Advisory Panel.

Mr. Chairman, within the past few weeks, the regulation of pesticides has become the victim of a well organized, shrill, and largely undocumented attack by a coalition of groups, some of whom declare themselves to be operating in the public interest. This assault on the integrity of Congressmen, Senators, pesticide users, EPA personnel, and others has led to a call for extensive amendments to FIFRA. We appreciate this opportunity to respond to some of these proposed charges, but let's look at the improvements that are being proposed.

The allegation is made that "the Agency (EPA) has proceeded at a snail's pace * * *" and "EPA, under both Democrats and Republicans, has been paralyzed by numerous unworkable provisions of the Federal act, lack of resources, and industry resistance." The process of reregistration should be given priority and subjected to specific deadlines, according to the proposal. If the deadlines aren't met, farmers will lose access to necessary crop protection chemicals.

Surely, we all wish for the highest possible rate of efficiency in this program as in all Government programs. But let's look at the improvements proposed. This special interest coalition proposes to require EPA to add an efficacy testing requirement as a further condition of registration. Apparently, this group believes farmers are too dumb to know if the weeds died after they were sprayed; and only EPA, or this coalition, is smart enough to make such a judgment. No evidence is presented to support such a charge, nor to indicate that any problem exists. Further, no estimate is provided as to the additional time, manpower, or money necessary to fulfill such[a requirement.

This miscellaneous collection of special interest groups would require EPA to consider potential health effects on "small" or "subpopulations." Presumably, this means EPA must identify the most sensitive people in the country and establish that such groups would not be harmed during pesticide applications, without regard to whether such groups were exposed. Clearly, persons with extreme respiratory ailments might be especially sensitive to the dust associated with handling some "wettable powder" products. It hardly makes sense to eliminate these products because someone, somewhere, might react. Again, this coalition submitted no evidence to establish that this hypothetical problem is real, and made no estimate of the time or money necessary to identify such groups, or test for their protection.

Their proposal would create a unilateral authority whereby the coalition or its members may require hearings on any and all registration requests. Last year, EPA processed over 35,000 registration petitions. This group proposes an open ended authority to delay each registration by a minimum of 60 days, and subject the process to literally millions of dollars of additional costs. Since they propose elsewhere that their attorney's fees should be paid by the taxpayer when they win, maybe they would like to offer to defray Federal and registrant costs incurred here when the registration is granted. There is no showing of how man or the environment would benefit from such authority. The only possible beneficiary would be the group that gains publicity from further delaying the process.

The group proposes to require denial of registration if any area of the country might incur a problem with the product's use. Perhaps they are unaware that EPA currently has authority to limit, rather than deny, registration requests based on a wide range of environmental variables at this time, and may limit the use of product by geographic criteria, methods of application, cultural practices—such as irrigation versus dry land farming—soil types and other characteristics. Under this proposal, it would be necessary to show that every place in the country, whether use was anticipated or not, would be OK. This hardly has any relevance to the existing law or the real world.

The group recommends that EPA should use the chemical sensitivity of children as a basis for registration standards. Certainly, raising the specter of poisoned children is a publicity gimmick useful for alarming the public and evoking emotional support, but it has no bearing on normal agricultural use of pesticides. Farmers do not make their children, or other people's children, lie in the fields during pesticide applications, nor do we love our children less than others love theirs. We are appalled by the shrill cries of a handful of self-serving individuals who suggest farmers are too callous or too profit motivated or blind to care about others. They present no evidence and have no case.

The proposal suggests that restricted use products be applied by certified applicators only, eliminating the "under direct supervision" category. No reason for this change is stated; no evidence of a problem is submitted; no claim of a benefit is cited. Over 1.5 million private applicators have been through the training/certification program since its inception in 1975. We believe participation of this magnitude is pretty good evidence of the agriculture community's commitment to professionalism and environmental sensitivity in pesticide handling and use. The number of farmers who have chosen to participate in this program far exceeds the number who use restricted use chemicals. Over 400,000 have recertified—upgraded their training—since the program began. What is the point of the proposed change? And again, where is the evidence?

The obstructionist group proposes to repeal a current requirement that EPA determine with credible documentation that "man or the environment" is harmfully exposed to a pesticide before taking action against the product. This proposal is puzzling indeed. A group, purporting to be concerned about the environment, doesn't want EPA to find out if the environment is being insulted, nor to have such information to serve as a basis for EPA action.

The capstone of illogic is the proposal to transfer farmworker protection to OSHA because "* * * OSHA has developed expertise in the area of occupational safety and health." OSHA's only adventure into this area was thrown out by the courts, in part because OSHA couldn't seem to distinguish between oral toxicity of pesticides and the hazard associated with dermal exposure. EPA has been building significant expertise and sophistication in the difficult areas of intermittent exposure, low levels of exposure to residues and degradation products, effectiveness of protective equipment, and enforcement. We suggest that those truly interested in farmworker protection do farmworkers no favor by suggesting a new agency be charged with reinvention of the wheel, new regulatory structures, new enforcement procedures, and the other bureaucratic factors which surely would not appear for years.

It should be clear that the cumulative objective of these proposals is not to achieve the stated objective of scientifically sound and more efficient pesticide registration and reregistration, but to negate the entire process.

Certainly, all of us consider ourselves environmentalists. We breathe the air, drink the water, eat the food, and raise our families as best we can. Poll after poll demonstrate broad public support for sound, aggressive environmental protection programs. Agriculture, by word and deed, is struggling to meet its environmental obligations and our progress in the past decade has been truly outstanding.

Although we use more pesticides now than in 1970, they are better researched chemicals used more skillfully and more judiciously than ever before. The science that supports these chemicals is the most extensive and expert in the world. The regulatory and enforcement program that oversees pesticides is elaborate and responsive. We don't say the system is perfect. Surely, it can be improved. But that improvement will come only from our objective and unbiased assessment of the facts, not from a legislated response to an emotional appeal for wholesale revisions based on half-truths, misrepresentations, and innuendo. Such efforts make a mockery of the term "public interest," and deserve none of this body's time.

Absent presentation of credible information supporting an alternative course, we recommend the committee report a 2-year reauthorization of FIFRA, with the Scientific Advisory Panel, and without further amendments.

Thank you.

Senator LUGAR. Thank you very much, Mr. Hawley.

Dr. Davies.

STATEMENT OF JOHN E. DAVIES, M.D., CHAIRMAN, DEPARTMENT OF EPIDEMIOLOGY AND PUBLIC HEALTH, UNIVERSITY OF MIAMI SCHOOL OF MEDICINE

Dr. DAVIES. Mr. Chairman, thank you very much for the opportunity and privilege to discuss with you this important topic.

My name is John E. Davies. I am a physician and professor of the department of epidemiology and public health in the University of Miami School of Medicine. I have been actively involved in medical aspects of human pesticide exposure for 20 years and have studied these in the United States and for the World Health Organization in many parts of the developing world. I am one of the original seven members of the FIFRA Scientific Advisory Panel and have served as the expert on epidemiology in this panel from December 1976 to September 1981.[1]

I would like to attempt to review the Agency's response to the pesticide program insofar as health is concerned, from an epidemiological perspective, looking at health items of the past, the future, and what I perceive to be the needs for the future.[1]

I believe that the key to understanding the health effects of pesticide exposure is to categorize the exposure in terms of the amounts, types, and durations of exposures sustained by man over time, and to study the disease end points associated with these different exposures. Current and past pesticide use patterns have resulted in three types of pesticide exposure categories as shown in the figure.[1]

This triangle addresses the peak acute exposure and its problems, and the middle component represents high chronic occupational exposure. The base of the triangle represents incidental exposure, represented by you and me, the public at large, and its exposures sustained in the home, in the air, and in the food.

The diseases associated with these exposures are different, and their recognition has evolved with time. About 10 years ago, pesticide poisonings were the main medical concerns, and the clinical manifestations we were seeing were either systemic poisonings or topical effects, primarily on the skin or the eye. Systemic poisonings were often fatal, and a cause-and-effect relationship between exposure and poisoning were obvious on a toxicological basis.

In those days, their magnitude was quantified on the basis of mortality and hospital morbidity statistics.

As time went on, and as a result of epidemiological studies and the occurrences of episodes of illness during the manufacture of selected pesticides, health effects of chronic exposure became recognized as well. These included, for example, neurological and behavior disorders, which were identified during the manufacture of Kepone, and with the use of Leptophos.

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[1] See p. 201 for the prepared statement of Dr. Davies, which contains the charts and tables referred to in his oral presentation.

Many of you will recall the epidemiological studies identifying male sterility with the use of Kepone, and other epidemiologic studies have identified an increase in lung cancer with inorganic arsenic. And so the health effects of chronic exposure is evolving with time.

More recently, with the recognition of toxic waste dumps and localized areas of excessive incidental exposure, public health concern has risen for the adverse health effects of excessive incidental community exposures to multiple chemicals. Many of the chemicals being identified in toxic waste sites are pesticides or contaminants of pesticides, and some of these are very toxic. They can be measured in the fat and the urine and the serum, and either the intact fat soluble pesticides are identified, or the metabolites of phenols of a growing group of pesticides, and the metals, of course.

The people who are exposed to these various categories of pesticide exposures are children, pickers, mixers, and applicators, subgroups which are at greatest risk of acute pesticide poisoning. The migrant workers, pickers, mixers, applicators and formulators are the occupational groups sustaining chronic occupational exposure to pesticides. The general public sustains incidental exposure to trace amounts of pesticides in our modern environment.

Looking at these categories, these various proved and unproved areas are still under investigation as being associated with pesticide exposure, and one can see that over the 10 years that EPA has sought to control these real and potential dangers by regulation and monitoring.

The goal of all these endeavors was to minimize or eliminate unwarranted pesticide exposure. The results were regulatory actions, which Mr. Johnson covered this morning, and which can be fitted into this triangle. We can see that registration, training, and certification of applicators are examples of regulatory actions which addressed the problem of the peak of the triangle. They were designed to prevent acute poisoning. Similarly, in the middle of the triangle, RPAR action, reentry times and again training and certification of applicators are directed to minimize occupational exposure. And last, for the general public's incidental exposures to pesticides, RPAR actions, tolerances, the cleanup of toxic waste, and its cancellation of certain persistent pesticides such as DDT and dieldrin have been directed toward the incidental exposure of the public.

Now, looking at these events, one tries to make an attempt to measure the outcome. One method to measure the efficacy of regulatory action is to compare the health related problems of pesticides in countries where regulation and training are still in the formative base, as is the case in many Third World countries. In the United States based on mortality statistics, the more serious pesticide problems are declining but in other parts of the world pesticide poisonings have now become a major public health problem.

For example, in Sri Lanka, 13,000 patients are hospitalized annually and 1,000 die. Another method of measuring the efficacy of regulatory action is obtained by measuring the health changes over time. Secular changes of certain persistent pesticides in adipose tissues of the United States general population is a case in point. The levels shown in the attached table show that the adipose concentration of DDT, beta-BHC, and dieldrin in blacks and whites in the United States from 1970 to 1978 has declined. Thus, for the white population in 1972 the decline for total DDT was 6.23 to 5.70, and so on, down to 3.64 in 1978. And the same goes for beta-BHC and dieldrin.

Insofar as DDT levels in blacks is concerned, it will be noted that concentrations have now declined to those levels which were seen in whites when DDT was canceled in 1972.

Presently, adipose specimens are collected, but remain unanalyzed because of budgetary constraints.

I believe these data are testimony to the regulatory actions of the Agency and the merits of monitoring by the Agency, and in my opinion highlight the need for future support for these adipose monitoring activities, particularly since there were 43 incidents of pesticides being found in the 425 toxic dumps which were listed by the Agency as being superfund priority sites.

In conclusion and for the future, my experiences on the Science Advisory Panel have led me to conclude that the Agency has done a creditable job with regards to its regulatory responsibility for pesticide exposure minimization and for the protection of man and the environment. While I am supportive of the need for the adherence of the guidelines for registration of new pesticides and the need for RPAR activities when appropriate, health risks are triggered by new data; I believe that the future needs of the Agency should be reordered with greater emphasis on the need for the cleanup of pesticides in the toxic waste dumps, and the need for stepped-up monitoring of pesticides in man and his environment.

The achievement of these goals, I believe, will only be possible with increased support and interdisciplinary approaches to the pesticide problem, which includes agriculture, industry, and the public sector, so that there can be a meaningful and an equitable input of research and monitoring for each of these parties with the Environmental Protection Agency.

Senator **Lugar**. Thank you very much, Dr. Davies.

Dr. Torgeson.

STATEMENT OF DEWAYNE TORGESON, PH. D., PROGRAM DIRECTOR OF BIOREGULANT CHEMICALS, BOYCE THOMPSON INSTITUTE FOR PLANT RESEARCH, CORNELL UNIVERSITY, ITHACA, N.Y.

Dr. **Torgeson**. Mr. Chairman, I welcome the opportunity to be here. My remarks will be limited to the Scientific Advisory Panel. And I should say that I am pleased that so far I have not heard anyone say that it should be done away with.[1]

From 1976 to 1981, I was privileged to serve as a member and chairman of the FIFRA Scientific Advisory Panel. And since September 1981 when the authorization ran out, myself and other members of the former panel have served as consultants to the Agency in a similar capacity, where possible, to help them.

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[1] See p. 206 for the prepared statement of Dr. Torgeson.

As you know, the Scientific Advisory Panel was created by an amendment to FIFRA in 1975. And the panel is charged with commenting as to the probable impact on human health and the environment of certain types of EPA actions, such as the cancellations, changes in classification, and proposed and final regulations.

During the 5- to 6-year period which the present committee—or former committee was active, we had a total of 52 meetings, ranging in length from 1 to 3 days, primarily in Washington, but on occasion located elsewhere. These meetings were always announced in the Federal Register 15 days prior, as called for. And this has insured that the participation and attendance at the meetings was very, very good.

Interested parties, they might be from the chemical industry; environmental groups, farmworkers, if that was the subject; grower groups, and individuals, would attend the meetings. And they were always given opportunities to present the information that they wanted to bring to our attention, pertinent to the particular subject we were addressing for the EPA.

In the testimony, printed testimony, I have listed for example in 1979 the types of things we covered. And I will not go through those. They are all there. I think if you look at them you will see we covered a broad range of subjects for the Agency.

There are a couple of things I would like to point out that I think have contributed to what I believe to be the success of the panel.

No. 1, the openness of the meetings; that we did offer a forum where all of these interested groups that wanted to address the subjects were presented, that were under review, could come. And sometimes it even got boring because they went on so long. But we did honestly try to enable everyone to have an opportunity to participate. And we listened.

I think another item that contributed to the success is that the panel's comments and recommendations are—because of the statute, are published in the Federal Register. And the Environmental Protection Agency has to respond to them. If they disagree, they have to state why, and I think this is helpful.

I think a committee such as this, which is mandated, and I think sometimes people were presumptuous in assuming that since we were mandated we were more an extension of Congress than part of EPA, but this did give us more clout than if we were a review committee that only answered to the Administrator of EPA.

A major factor in the success of the panel—and I think this is something that for future panels should always be watched—the composition of the panel. I think we were very fortunate in having a composition of toxicologists, biologists, epidemiologists and so forth that really served very well. And certainly it was one of the most enjoyable experiences I have ever had working with this group. I should say perhaps that I learned more than I felt I contributed because of the type of people that were on it.

Nevertheless, they brought into the group a lot of different types of backgrounds and experiences that could be brought to bear on the items before us. And in those cases where we did not have the expertise, we were permitted to bring consultants in as well.

No. 4, another reason that contributed to success is to have a good executive secretary, which we had two of them during that period of time, and the supporting staff, which is very essential to operations such as this. We met almost once a month; there was a lot of paperwork.

The panel was very hard working; we spent many, many hours over huge volumes of material furnished by the Agency as well as other interested parties. I believe the panel always tried to be objective in addressing the science of proposed actions. This is not easy since all of the facts are not always available to be presented to us

I think we were successful; although we certainly made—we must have made some errors; I'm sure we did, in judgment.

I think that the independence of the panel in arriving at their decisions and comments and recommendations is evidenced by the fact that at times the Agency was happy with what we decided; other times, they were unhappy. And likewise, the industry groups and the environmental groups and other groups were sometimes happy and sometimes they were unhappy with our decisions, which I think showed that we were at least acting freely.

I firmly believe that the panel has served a useful purpose in helping the Agency, and I think that we always tried to help the Agency in reaching wise decisions. And I certainly believe that it should be continued. I think the 5-year period is an ideal period in that it does permit you to have some stability to the panel.

Thank you.

Senator LUGAR. Thank you very much, gentlemen.

Dr. Davies and Dr. Torgeson, perhaps inadvertently or deliberately you have not addressed the reauthorization question or the funding question.

Do you have any judgments on that or is the burden of your testimony more specifically with regard to the advisory panel?

Dr. TORGESON. Well, mine was certainly more specific to the advisory panel, as I said, in my preface. However, I think FIFRA overall certainly should be reauthorized. I think it has played an important role.

As you heard today, I think people will find things wrong with it. I think some of the problems with the things that are wrong with it is perhaps things that are administered and so forth. And I think the panel had a role in ironing those things out. But we have to move along with it.

Senator LUGAR. Dr. Davies, do you have a comment?

Dr. DAVIES. I certainly think that FIFRA should continue. It is a very important service.

Senator LUGAR. Let me ask you, Dr. Davies: The table that you have presented, the amounts of residue in adipose tissue of persons that have been tested, it would appear that in 1978, the amount of DDT increased in both black and white citizens that were tested after what appears to have been a fairly steady decline prior to that time.

Do you have a comment on why things took that turn in 1978, the last year that you have in your tables?

And do you have any idea of what has happened subsequently to 1978?

Dr. DAVIES. No, Mr. Chairman, I don't. Certainly I got the impression that there may be a leveling off, at least in the blacks. And your point is very well raised because I think it is critical that we keep this background, this watchdog of what is happening. And it has bothered me to find that there is no plan of continuing monitoring in this and other facets in our environment. Just to know what they are doing is virtually important.

Senator LUGAR. Once again, you have touched upon this, but why is there no testing going on presently? And what needs to be done in order to provide—I think you have suggested in your conclusions that you are supportive in the need for hearings and guidelines and what have you, but that the Agency ought to put greater emphasis on the need for pesticides and toxic waste dumps and stepped up monitoring of pesticides for man and environment.

How do you propose—or what do you propose might be helpful in those respects?

Dr. DAVIES. I think that these are biological exposures. There are very complex interpretive problems when you find high residues in certain places in the soil and so forth. What really matters is what is in man. And we found a lot of differences between what is around man and what is in man.

We don't know how long they stay. We don't know what's happening to them. And the average person's greatest concern is what's in me, what's it doing, and what's it going to mean. And there is a whole fundamental need to evaluate what I call a pollutogram, so that we can interpret it and bring some credibility to this.

Senator LUGAR. Now, who is performing this program that provided the data that you have given to us this morning?

Dr. DAVIES. This is the national—the Federal Government is performing this, the EPA is doing it. It is the national human monitoring program. It collects a stratified sample of fats obtained by biopsy from, I think, it is something like 75 hospitals or more in the United States, and gives a picture of incidental exposure.

So the United States is doing it; it is being done in different labs. And the labs are all part of a very tight quality assurance program.

Senator LUGAR. But by EPA? What time did EPA stop doing this?

Dr. DAVIES. As you can see, the data goes up to 1978. I don't know when they stopped. But I understand now that there are no funds to continue monitoring pesticides in the population.

Senator LUGAR. I see.

What would you recommend with regard to the cleanup for pesticides and toxic waste dumps? You have suggested that ought to be a greater emphasis of the EPA.

Dr. DAVIES. Yes.

Senator LUGAR. And did the Science Advisory Panel monitor that situation, too? Were you taking a look at waste dumps——

Dr. DAVIES. It's very interesting. Dr. Torgeson worked with me on this possibility at our very first meeting back in 1975 and 1976. We were advising the Administrator as to what to do with certain pesticides. It was a serious problem then for, if you cancel a compound what do you do with it? How do you dispose of it? We urged the Agency to be very definitely concerned with this because it follows a cancellation.

Senator **Lugar**. I very much appreciate your coming, all three of you, to testify as you have on behalf of the panel and with regard to the legislation as a whole.

And this concludes our hearing. The findings from our hearings will be reported now to the full committee for additional action.

We appreciate your coming. This hearing is concluded.

[Whereupon, at 12:15 p.m., the subcommittee adjourned, subject to call of the Chair.]

APPENDIX

STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM VERMONT

Mr. Chairman, I want to thank you for the opportunity to discuss this morning a matter which concerns me greatly.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is supposed to govern the use of pesticides, herbicides, and other chemicals in this country in a manner which protects the public's health and safety and the environment.

FIFRA is also supposed to ensure that farmers, ranchers, and others have the necessary tools to control weeds and pests without endangering their health and that of their workforce.

Mr. Chairman, the Reagan Administration Environmental Protection Agency (EPA) has failed to enforce the law on both counts.

The recent spate of alleged violations of our environmental laws by the Reagan EPA did not exclude the Office of Pesticide Programs. Dr. John Todhunter, former Assistant Administrator for Pesticides and Toxic Substances resigned his office under a hail of alleged abuses of FIFRA and other laws under his jurisdiction.

Dr. Todhunter had initiated a series of so-called "decision conferences" at which pesticide registration decisions were reached behind closed doors among EPA officials and the affected industry.

In the 1978 FIFRA conference report, these closed door negotiations were specifically rejected.

Mr. Chairman, the number of "emergency," "conditional," or "special local needs" registrations has increased dramatically under this Administration.

These special conditions were written to meet emergency situations, not serve as a mechanism for backdoor registration of pesticides and other chemicals.

Yet, under the Reagan EPA, the number of these special registrations increased by 430 percent according to a House subcommittee report.

Mr. Chairman, the recent EPA report detailing alleged fraudulent activities on the part of Industrial BioTest Laboratories (IBT) only adds to the mounting evidence of the need to reform FIFRA registration procedures.

That report found that fully 15 percent of all pesticides used in this country were registered on the basis of faulty IBT data. All 212 pesticides reviewed by IBT had been subjected to at least one invalid test.

Last year, I warned this Committee about IBT data and the need to preserve the public's access to critical health and safety information. The public serves as a valuable check against the use of this kind of material.

Yet, the Reagan Administration instead pressed for even more restrictions on information. This Committee rejected that proposal.

Mr. Chairman, FIFRA is not a perfect law.

But is is the law. Instead of enforcement, however, the Reagan Administration has, thus far, focused its attention only on the loopholes in FIFRA and how they can be taken advantage of.

Well, Mr. Chairman, I believe it is time for this Committee to focus on improving FIFRA, to reform current law and close the loopholes so that further abuse cannot occur.

Mr. Chairman, this Committee should look closely at several areas of the FIFRA registration process.

First, public participation in pesticide registration decisions must be strengthened.

Currently EPA is required to publish notice in the Federal Register of a pending pesticide or other chemical registration and allow 30 days for public comment.

However, EPA is not required to disclose the safety tests used to reach their conclusion until 30 days after a registration decision is reached.

Mr. Chairman, it is obvious that this procedure must be changed.

Second, public access to health and safety data, and the tests used to generate this data, must be guaranteed. Public review of this information serves as a vital check against possible abuses of FIFRA registration procedures.

Third, the re-registration process at EPA has slowed to a crawl.

In the 1972 amendments to FIFRA, EPA was required to reevaluate all currently registered pesticides for their potential to cause cancer, genetic mutation, birth defects, and other health hazards.

EPA was originally given until 1976 to complete this process. In the 1978 FIFRA amendments, EPA was given more time.

Yet, in recent testimony, EPA said it would be 1991 before all re-registrations were completed.

Mr. Chairman, EPA must quicken this pace. According to a House subcommittee report, at least 62 percent of all pesticides now used have not been adequately tested for their potential to cause cancer and some 60-70 percent have not been adequately tested for their potential to cause birth defects.

Millions of tons of herbicides and pesticides are applied in this nation each year. They are in our food, our water, and in our air. EPA must move more quickly to determine whether or not these chemicals pose a health hazard.

Mr. Chairman, because of these and other concerns I have with current FIFRA procedures, I support a one-year reauthorization of current law. I have a letter here from Senator Proxmire, and other Senators supporting a one-year bill. I ask that this letter be made part of the hearing record.

I know the Administration supports passage of a two-year reauthorization of FIFRA.

Yet, a two-year bill will only allow the current problems with FIFRA to fester and perhaps worsen.

Enactment of a one-year bill will accomplish several important goals.

First, it will allow new EPA Administrator William Ruckelshaus time to reorganize and clean up the Office of Pesticide Programs.

Second, it will allow this Committee time to study carefully over the next year possible reforms to FIFRA.

Third, this Committee will fulfill its legal responsibility to pass a FIFRA reauthorization bill.

This action will allow us to monitor Mr. Ruckelshaus' progress, study proposals of the environmental community and industry, and then come back next year to enact changes in the law that we may deem necessary.

U.S. SENATE,
Washington D.C. May 18, 1983.

Hon. JESSE HELMS,
Chairman, Committee on Agriculture,
U.S. Senate, Washington, D.C.

DEAR SENATOR HELMS: As you are aware, the U.S. House of Representatives has passed a one-year reauthorization of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). We believe that growing public concern about the failures of the current statute to protect public health and safety makes a one-year authorization the most sensible course of action for the Senate. Therefore, we urge the Senate Agriculture Committee to follow the lead of the House.

We believe the Committee must deal with questions surrounding the validity of existing chemical company studies as soon as possible. Fifteen percent of all pesticides now on the market were registered with allegedly fraudulent data supplied by the Industrial Bio-Test Laboratory which is now the subject of criminal proceedings. The Committee should also address findings of recent GAO reports and a study by the House Agriculture Committee subcommittee on Department Operations, Research and Foreign Agriculture which point out troubling deficiencies in the Act.

At this time perhaps more than ever before, the public needs to know that the Congress is reviewing this program and is ready to take action. However, a two-year reauthorization sends the false signal that all is well with the pesticide program.

The public has become acutely aware that the U.S. Environmental Protection Agency does not always offer the protection it was meant to provide. Similarly, many in health, farm, labor, consumer and environmental groups have told us that FIFRA, too, is inadequate.

Given the range of concerns about pesticide safety, we urge the Committee to report out a one-year reauthorization and immediately to begin considering major issues of public safety and possible legislative remedies.

Sincerely,

William Proxmire,
Howard M. Metzenbaum,
Alan Cranston,
Christopher J. Dodd,
Jim Sasser,
Carl Levin,
Dale Bumpers.

Statement of Hon. Walter D. Huddleston, a U.S. Senator From Kentucky

Mr. Chairman, the people of this Nation, concerned about their environment, want the Government to ensure the safe use of pesticides. On the other hand, farmers, the pest control industry, those involved in disease control, and all of us who benefit from the use of pesticides expect the Government to provide reasonable and efficient regulation of pesticides.

The Environmental Protection Agency has the difficult job of dealing with these competing interests and balancing the risks and benefits involved in the use of pesticides.

We in Congress have the responsibility of providing EPA with the legislative direction and authorities that the Agency needs to do its job effectively.

I believe that the current law is a good base for the EPA pesticide program. Nonetheless, as changes in the law become necessary to make the program successful, I will work to achieve such changes.

The Environmental Protection Agency has requested only a reauthorization of appropriations, and an extension of the FIFRA Scientific Advisory Panel, at this time. Of course, as we all know, the new management of EPA is just now beginning to settle in at the EPA. I am sure Mr. Ruckelshaus and his assistants would appreciate at least a short grace period before Congress considers revising the Statutes over which EPA has jurisdiction.

Therefore, I hope the witnesses today will address the issue of whether a simple reauthorization of appropriations is sufficient at this time, and look forward to hearing the testimony.

Statement of Hon. Paul S. Sarbanes, a U.S. Senator From Maryland

Mr. Chairman: I appreciate the opportunity to appear before you this morning to discuss a matter of major importance, which should, in my view, be carefully considered by the subcommittee during its review of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). As you know, I have introduced legislation, now pending before the subcommittee, to require the Environmental Protection Agency to maintain and utilize an in-house facility for conducting biological tests on pesticides and the other chemicals covered by FIFRA. I would like to outline this morning why this legislation is necessary and important.

Until about a year ago, the EPA maintained a laboratory for testing the biological effects of chemical products. The lab, which was located on the grounds of the Beltsville Agricultural Research Center, was capable of doing investigations in toxicology, virology, microbiology, and plant biology. Over the years, the laboratory had done important work in the routine screening of products—especially disinfectants—where the products' efficacy had major public health implications. In addition the labs were used to do special studies of products that had come into question; to periodically retest for degradation a random sample of products already on the market; to do expedited tests for emergency registration requests; and to help establish scientific test standards and procedures to be used by outside laboratories.

I have attached a statement summarizing some of the major achievements of the Beltsville biological laboratory. I would also like to include in the record a number of letters from state environmental and agricultural officials as well as university researchers attesting to the importance to the Beltsville laboratories. It should be clear that the lab was well run, well thought of, and engaged in work with direct impact on the protection of public health and the environment. The lab also provided a useful function to industry as a central point for setting standards and resolving disputes over ambiguous data.

In the face of this evidence, I was surprised and disturbed to hear in late 1981 of plans to close the biological laboratory. Although the lab first came to my attention because of its location in Maryland, I came to realize that it served a unique and important national role. This laboratory was the only federally owned facility in the country equipped for and experienced in conducting biological testing. For this reason, I vigorously protested the proposed closing. Notwithstanding my objections and those of informed people around the country, EPA began to phase out work at the laboratory during early 1982 and has subsequently reassigned all of the technical personnel to non-laboratory positions. The laboratory has not been in operation since April, 1982.

Without an in-house biological laboratory, the EPA is incapable of carrying out independent, objective tests to verify data regarding safety and efficacy being submitted by manufacturers. The EPA is also incapable of responding to emergency requests from states or from other EPA units for tests on products involved in accidents or otherwise suspected of being unsafe or ineffective. The EPA is similarly incapable of responding to emergency registration requests where expedited testing is required. Infestations such as the Medfly, fireant, or gypsy moth, often result in intense political pressure for quick action and require an ability to rapidly provide test data that is above question. In my view, the EPA decision not to maintain its biological testing capability amounts to a serious abdication of the responsibility for the protection of health and environment which Congress has entrusted to the agency.

The rationale provided by EPA to justify closing the laboratory is seriously flawed in many respects. The EPA has argued, for instance, that the testing done at the lab duplicates testing done by private labs in connection with a registration application. This argument completely ignores the need to be able to verify data and to spot inaccurate data. The recent news accounts about the ongoing case against IBT point out the need for healthy skepticism about industry supplied data. I would argue that the EPA should pursue a much more vigorous policy of lab audits and independent verification than has been the case to date. At the minimum, however, the EPA should maintain capacity to verify and spot check data from other sources.

The EPA contends that market forces can be expected to weed out products that are not effective. The problem is that market forces can only come into play after a product is in use by the public. In the case of chemicals whose unanticipated effects or lack of effect may have major health and safety consequences, reliance on market forces is clearly inappropriate.

The EPA has argued that much of the testing formerly done at Beltsville can be replaced either by testing by the states or by testing on an as needed basis by arrangement with other facilities. There are a number of problems with this approach. For one thing, 47 states do not have the capacity to do biological testing. As Thomas Irvin, Georgia Commissioner of Agriculture wrote in a letter to EPA . . . "there is absolutely no other facility available to the states which can act as a clearinghouse for biological methodology and provide to the states the biological support they must have if they are to undertake the routine assays of these health-related pesticides."

Maurice Rowe, Virginia's Secretary of Commerce and Resources pointed out to EPA that one can also question the wisdom of "closing an existing well run facility versus 'gearing up' many state laboratories to do virtually the same job."

A program where the government could only obtain test data by contracting with private labs would be, in my view, inappropriate for the type of testing involved. Virtually all of the laboratories capable of competing for such contracts are closely tied to clients in the chemical industry and would therefore be subject to at least the possibility of conflict of interest. The idea of using a Fish and Wildlife Service laboratory in Denver for some work is similarly flawed in that the Interior Department itself is heavily involved in submitting pesticides for registration. Furthermore, the Denver laboratory does not have the equipment, experience or expertise to do such testing.

I fully recognize that you are faced with a number of difficult issues in considering what changes to make in FIFRA itself and in the way the Act is administered by the Office of Pesticide Programs. Some serious problems are outlined in the GAO report and in the House Agriculture subcommittee's staff report. These raise questions about the quality of science within OPP, the pressure to reduce backlog at the expense of careful review, the quality and reliability of data on file from earlier testing, and the effectiveness of incident monitoring and laboratory auditing systems. I recognize that steps to resolve these and other issues will take careful consideration and will require building a consensus that may be difficult to achieve. I would be glad to work with my colleagues on the subcommittee in any way that might be helpful to resolve these issues.

In the meantime, I would ask the subcommittee not to allow the EPA to create more problems for itself, and ultimately for the Congress by permanently eliminating its biological testing capability. Whatever specific steps the subcommittee might eventually recommend to adress problems in the pesticide program, it seems clear that in this issue the EPA is moving in the opposite direction. As I have indicated, the in house biological laboratory provided an important capability, was well run and well thought of by both industry and end users. It was a known quantity and at this point could be reopened relatively quickly. The alternative is to have no biological testing capability in the short run. In the long run we would be committed to a system that is completely untried and, in my view, conceptually flawed.

I believe the choice is clear and I urge the subcommittee to act favorably on the legislation I have proposed.

This concludes my prepared remarks. I would be happy to answer any questions you might have.

[The following material and articles were inserted by Senator Sarbanes:]

EXAMPLES OF BELTSVILLE EPA BIOLOGICAL LABORATORIES ACCOMPLISHMENTS

1. The Beltsville Pharmacology and Animal Biology laboatories conducted extensive mammalian feeding studies of the pesticides chlordane and Endrin to determine toxicity levels with respect to concentrating in the liver and brain.

The results of these studies played a significant role in the cancellation and/or phasing out of these chemicals which are suspected carcinogens.

2. The Beltsville Animal Biology Laboratory conducted tests on chemical bombs used to control or eliminate disease-bearing rodents. The laboratory found these bombs to be extremely dangerous because of possible explosion in the hands of the user. Results reported to headquarters for regulatory decision. Bombs were later removed from the marketplace. (Note: an instance of serious human injury occured when a bomb (Giant Destroyer) was used by Virginia judge. Previous to this a similar product caused a human death).

3. In its routine analyses of Malathion products which are generally considered safe and extensively used by farmers, the Beltsville Toxicology Laboratory discovered an extremely toxic product which could have caused death or serious injury to the user within a relatively short time after exposure. The product (Red Top Malathion) was contaminated with the extremely toxic chemicals TEPP or Parathion.

4. The Beltsville Plant Biology Laboratory conducted a test consisting of about 50 treated and non-treated elm trees to determine the efficacy of a federally registered product claiming control of Dutch elm disease. The preponderance of the data collected indicated that the product was of no value against the disease. The product was removed from the marketplace both in the United States and Europe.

5. The Beltsville Plant Biology Laboratory extensive field tests on the drift problem of powdered 2,4 D products which were extensively used to control weeds in the production of food crops. These tests showed significant damage to adjacent broadleaf agricultural crops resulting from the inherent characteristics of this type product. Because of these tests, the use of this type product is no longer allowed.

6. The Animal Biology Laboratory performed multiple tests to determine the efficacy and potential hazards to wildlife of the pesticide 1080 which is used for rodent and coyote control in the west. This data is being used in developing a final regulatory decision.

7. The Beltsville Plant Biology Laboratory conducted a special study for the State of Maine to settle the question of the misuse of the herbicides Picloram and 2,4 D which were used by the St. Regis Paper Company to control undesirable undergrowth. The results of the study indicated that the soil suspected of contamination by the alleged misuse was fit for crops for the following season.

8. *DBCP—a known human sterilant.*—The Plant Biology Laboratory was assigned the task by OPP to determine the life of DBCP in agricultural soil. The results showed that high levels of DBCP existed in the soil 6 months following treatment. This information was contrary to that provided by the manufacturer.

9. The Beltsville Microbiology and Virology Laboratories testing program found that approximately 40% of EPA registered hospital disinfectants (also used in nursing homes, children day care centers, etc.) were found to be ineffective against the following organisms.

Staphylococcus aureus; Causes internal and external infection to the body and is implicated in food poisoning.

Salmonella choleraesius; Causes paratyphoid fever and is implicated in food poisoning.

Pseudomonas aeruginosa; Causes fatal skin infections in burn patients.

[Reprint from the New York Times, Monday, May 16, 1983]

THE SCANDAL IN CHEMICAL TESTING

There is an appalling rent in the safety net that protects the public from hazardous chemicals. New compounds must be tested by law, but what if those hired to do the testing cut corners and fabricate the results? According to a Government study released during a trial now under way in Chicago, 15 percent of all the pesticides on the market have been certified safe on the basis of one or more tests now thought to be invalid.

The tests in question were performed by Industrial Bio-Test Laboratories, four of whose former executives stand accused of providing false data to chemical companies. The companies presented the data to the Government to prove that their products were safe for market.

The charges against I.B.T. are alarming because of the enormous number of different chemicals it tested. The Environmental Protection Agency's study examined I.B.T.'s data on 200 pesticides. So far 66 percent of the tests have been judged invalid, only 19 percent acceptable.

I.B.T. has also tested herbicides, food additives, cosmetics, drugs and other products now on the market. The public will be at risk during the time it takes to sort out which of these products were wrongly or prematurely judged safe.

According to an article in The Amicus Journal based on grand jury testimony disclosed by I.B.T.'s attorneys, many of I.B.T.'s test animals were housed in a waterlogged room, known as "the Swamp": "Dead rats and mice, technicians later told Federal investigators, decomposed so rapidly in the Swamp that their bodies oozed through wire cage bottoms and lay in purple puddles on the dropping trays," Mortality was so high that it was impossible in some cases to assess the affect of the chemical under test, the article says.

I.B.T. tested products for many of the country's major chemical companies. How then could the scandal remain undetected for so long? Despite the apparent extent of the problem, many who relied on I.B.T.'s services failed to notice anything amiss. The problem was discovered only by accident, when a Government official looking for something else pulled out a file of I.B.T. data by mistake.

At the Food and Drug Administration, a scientific auditing unit quite regularly turns up false or suspicious data. Since only the most carelessly fabricated data are easy to detect, this may be the tip of the iceberg. The Environmental Protection Agency, however, has no such unit. As a large consumer of such product test data, it should institute one without delay, and appoint enough toxicologists to assure quality.

A stronger measure would be to give chemical companies an institutional responsibility for the test results they present. Instead of being contracted out to private laboratories, the safety tests might be conducted at an institute supported by the industry, perhaps with Government participation. Such an institute would have a reputation to protect, and the independence to report any safety problems.

Test results might not flow as fast and freely as those from compliant private testers. But the public and the chemical industry now share a clear interest in avoiding another scandal.

[Reprint from the New York Times, May 12, 1983]

E.P.A. FAULTS TESTS ON 200 PESTICIDES—WORK BY A LABORATORY INVOLVES CHEMICALS NOW ON MARKET

(By Philip Shabecoff)

WASHINGTON, May 11.—A study by the Environmental Protection Agency has found that two-thirds of all tests conducted by a big private research laboratory to establish the safety of pesticides and herbicides now on the market are scientifically invalid.

The report, which took five years to prepare, finds that virtually all 212 pesticides and herbicides cleared by Industrial Bio-Test Laboratories of Northbrook, Ill., were subjected to at least one invalid test. Many of the pesticides and herbicides are in wide use, including Captan, Paraquat, Lasso, Machete, Orthene and Carbofuran.

Agency officials said the report raised what one of them called "big questions" about the chemicals tested by the company that are still on the market.

But the officials, who asked not to be identified, said the fact that the tests were invalid did not necessarily mean the chemicals posed a threat to human health or safety. It did mean, they said, that new information had to be obtained about the health effects.

The data produced by the laboratory were used by manufacturers to gain Government approval for marketing the chemicals.

The 212 chemicals represent 15 percent of all chemicals registered by the E.P.A., so the invalid tests of the Chicago laboratory could pose a significant problem. There are 44 chemical manufacturing companies involved, many of them major ones such as DuPont, Dow, Monsanto, Ciba Geigy, Olin, Velsicol, and Hercules.

The tests were conducted to see if the chemicals posed threats of cancer, birth defects, genetic damage or other health problems.

The environmental agency officials said the agency did not have authority under the Federal Insecticide, Fungicide and Rodenticide Act to order those chemicals that were not adequately tested off the market. That cannot be done until the agency has made a finding that use of the chemicals poses a risk of "unreasonably adverse effects."

ALL WE HAVE ARE QUESTION MARKS

"All we have now are question marks," an official said.

The officials remarked, however, that the flawed testing at least raised the possibility that some of the chemicals could present unknown hazards to public health.

The officials said they had not finished evaluating their findings about the Industrial Bio-Test data and did not know how much more information they would need. They said that where the invalid tests were crucial to the information needed to validate the safety of the substances, the chemical manufacturers would be asked to submit new data in support of keeping them on the market.

Four former directors of Industrial Bio-Test are now on trial in Federal District Court in Chicago on charges of misrepresenting data used by the chemical manufacturers to obtain Government approval for the chemicals.

The 212 chemicals tested by the Chicago laboratory are being examined by the environmental agency in cooperation with the Government of Canada, where many of the pesticides and herbicides are also used. The Ottawa Government has refused to permit the use of 16 of the chemicals until questions raised by the Industrial Bio-Test problems are resolved.

The World Health Organization is also examining the implications of the invalid tests.

But the E.P.A. officials said that the fact that the chemicals were subjected to one or more invalid tests by Industrial Bio-Test did not necessarily present a serious problem. In many cases, there was a wide base of data from other sources that provided sufficient assurances of their safety.

On the other hand, even if past tests on chemicals were scientifically valid, it does not mean they were adequate, they said, explaining that new standards often required different tests.

A number of companies voluntarily submitted new data to the agency after the allegations about the laboratory were made public, the officials said.

FAULTY PROCEDURES CHARGED

The report says only that the tests were invalid because they failed to adhere to accepted scientific procedures. It does not address allegations brought at the Chicago trial that test results presented by the laboratory were fraudulent.

Government lawyers have charged that the company falsified such things as the number of deaths among test animals that were subjected to the chemicals.

The E.P.A. officials said they would have reviewed most of the chemicals tested by Industrial Bio-Test in their normal routine of administering the pesticide law. But their five-year concentration on the laboratory's tests was out of the ordinary, they said.

One official said the pattern of invalid tests found at the Chicago laboratory was "unprecedented" and had "shocked" toxicologists around the country.

The existence of the E.P.A. report was mentioned at the Chicago trial. A copy of it was given to a reporter who requested it.

[Reprint from the Baltimore Sun, May 6, 1983]

ADMINISTRATION HALTS EPA DISINFECTANT TESTS

(By Vernon A. Guidry, Jr.)

WASHINGTON.—The Reagan administration has put an end to an Environmental Protection Agency biological testing program that had been turning up high rates of failure in testing the effectiveness of disinfectants used by hospitals.

EPA has gone to other means of checking the disinfectants, but officials acknowledge their system is not completely in place, even though the agency began cutting back its in-house testing program in 1981.

Critics maintain there is no substitute for the independence, expertise and experience of the EPA biological testing laboratory in Beltsville, where the difficult procedures involved in biological testing were carried out.

In defense of the action, EPA pesticides chief Dr. John A. Todhunter said last year that in the interest of efficiency, tests already conducted by manufacturers should not be repeated at Beltsville.

"In this instance, we must rely on the integrity of manufacturers and the laboratories which they may employ to perform . . . tests and the interest of the user community in assuring efficacious products," he said.

Although the issue has been smoldering for more than a year, it has received little attention outside the industry, even among users. A spokeswoman for the American Hospital Association in Chicago said yesterday that the organization was not aware of high failure rates in disinfectants subjected to EPA testing

That is beginning to change as EPA comes under scrutiny over allegations that it has gone too far to accommodate industry on a number of environmental and health issues. For instance, the March issue of a small trade publication, Hospital Infection Control, asks in its lead story: "Who guarantees that the disinfectants in your hospital are efficacious?"

The answer the publication comes up with is, for the most of the nation no one.

The EPA maintains that it is doing the job, but state officials, scientists and Senator Paul S. Sarbanes (D, Md.) challenge that assertion.

Mr. Sarbanes said at week's end that the decision to halt disinfectant tests as well as biological testing on the effects of other pesticides at Beltsville was "outrageous and raises serious questions about the EPA's ability to comply with its responsibilities to the people for the protection of the environment."

The disinfectants in question are used to kill infection-causing bacteria in hospitals, nursing homes and other health-care facilities.

According to a former EPA employee and to an account in the trade press, as many as 50 percent of the hospital disinfectants tested at Beltsville failed to meet effectiveness standards.

Warren R. Bontoyan, chief of the EPA laboratories in Beltsville, says he does not recall the exact figure. "It was pretty high. Probably in the area of 30 to 40 percent."

James G. Touhey, director of benefits and field studies in EPA's pesticide office, says those tests have been "reviewed" and the failure rate is still lower.

"It would not be farfetched to say 25 percent have failed to pass the test standard," Mr. Touhey said. He cautioned that this was not 25 percent of the disinfectants on the market, but rather 25 percent of those for which suspicions of some sort were raised. He had no estimate of how large a share of the total market they comprised.

Even so, all involved acknowledge that the rate is high.

"Quite frankly, we've been examining this extensively in-house," Mr. Touhey said in an interview. "The level of failures . . . are—even as you lower them—significant, and we are looking at these problems."

Mr. Touhey said it was possible the Beltsville facility could be revived, but in the meantime, the EPA is sticking with a program of examining data required of industry on the products' effectiveness. It is considering an expansion of the existing laboratory audit program to check the performance of outside laboratories.

No one contacted on the matter said he knew of direct pressure from industry to cancel the Beltsville biological testing. Chemical testing still goes on there.

But several sources cited the Reagan administration's general posture at EPA to rely more on industry and market factors in place of government regulation and examination.

Mr. Bontoyan said he knew of no industry pressure. But he added that "I'm certain industry wasn't happy about what we were finding out here."

The industry trade association for some 50 to 60 disinfectant manufacturers is the Chemical Specialties Manfacturers Association in Washington, headed by Ralph Engel.

"Sure, there were some people unhappy about the results, but generally I've not heard anybody say to me that they prefer the Beltsville laboratory be closed," Mr. Engel said yesterday.

The trade association chief said he was unaware of any failure rates of even 25 percent, saying he had heard of percentages ranging from 7.6 percent to 12 percent in state laboratories. The EPA offers grants to states seeking to make their own tests. Florida, North Carolina and Virginia have done so.

Mr. Engel said the closing of Beltsville has contributed to another problem for the industry. Because of the difficulty of this kind of testing, the industry has seen the same batches of disinfectant win approval in one location and fail in another.

This issue has placed the industry and EPA at odds and prompted a major review of testing procedures involving the agency, the industry, the states, outside laboratories and the Association of Official Analytical Chemists.

Mr. Touhey says the manufacturers say testing procedures are the problem now "It is our position that that is not the case," he adds.

Once this issue is settled, he goes on, the EPA can take a look at its overall program, and perhaps extend its existing laboratory audit program to include checks on the accuracy of private labs that test disinfectant effectiveness. That is not being done now.

Word of the EPA's plans began circulating among concerned state agencies and academics in mid-1981 and brought the first wave of opposition. One opponent was long-time FDA and EPA consultant Frank B. Engley, a professor of microbiology at the University of Missouri.

He wrote to the EPA expressing "considerable disbelief and dismay" at the plans. The kind of tests involved, he wrote, can produce greatly differing results depending on the way they are conducted. "It's extremely important to have a governmental laboratory checking on the claims made by any and all companies," he wrote.

Such test, he went on, have an impact on the "health of the 35 million people who go into hospitals each year and to unknown millions" in other health care facilities.

In a telephone interview this week, Dr. Engley said his views had only been reinforced over time. He said the laboratory was the "only real check and balance we have on the efficacy of disinfectants for hospitals, nursing homes and other health care facilities."

To cut it out for economic reasons, he said, "is a hell of a way to save money."

Thomas T. Irvin, Georgia commissioner of agriculture under whose responsibility such testing falls, said yesterday that he still opposes the action.

He wrote to the EPA in the fall of 1981 that "there is absolutely no other facility available to the states which can act as a clearinghouse for biological methodology and provide to the states the biological support they must have if they are to undertake the routine assays of these health-related pesticides."

To cut out the Beltsville facility, he wrote, "would be tantamount to delegating [pesticide] use enforcement to the states and then 'pulling the rug out from under us.' "

Maurice B. Rowe, who was then Virginia's secretary of commerce and resources, wrote in the fall of 1981 that the EPA ought to reconsider the merits "of closing an existing and well-run facility versus 'gearing up' many state laboratories to do virtually the same job."

Senator Sarbanes said he "strongly opposed the administration's decision last year to cease operations at the laboratory. This unjustified action is consistent with the administration's insensitivity to envionmental concerns. The Beltsville facility was the only in-house laboratory equipped to test for the biological effects of new pesticides. It was also the only federal facility for checking the effectiveness of hospital disinfectants and fungicides."

The senator attempted last year to generate opposition to the move, but staff members believe his effort to call attention to the substance of the issue were thwarted by a perception that it was merely a pork-barrel issue for a Maryland senator.

The biological laboratories had a budget in fiscal 1981 of about $600,00 and had about 20 employees.

The laboratory has not been officialy closed. The buildings are still maintained but the microbiologists have been transferred to EPA headquarters to do the "desk reviews" of industry effectiveness reports and other duties.

[Reprint from the Washington Post, April 1, 1983]

SOLE NATIONAL LAB TESTING DISINFECTANTS FOR USE IN HOSPITALS IS CLOSED BY EPA

(By Phillip J. Hilts)

The only national laboratory to test the effectiveness of hospital disinfectants has been closed down by the Environmental Protection Agency.

The loss has created a chorus of dissent from state officials, industry leaders and scientists, some of whom say they fear that hospital infections may result from bad batches of disinfectants and sterilants in the 47 states where no laboratories are testing them for efficacy.

James G. Touhey, director of benefits and field studies for the EPA, said that his office believes there is "not a high probability" that people will get infections as a result of closing the laboratory.

He said that the agency wants to use the 20 or so employes who had been working in the laboratory to reduce the backlog in other jobs, such as reviewing registration applications for new pesticides.

Touhey insisted that the decision is not intended to save money, since very little money will be saved.

He said that the decision was made to concentrate manpower on new applications from companies, and so scicentists were taken from the EPA laboratory.

Touhey said that there is another check on disinfectants, which leads him to believe that there is little danger in closing the EPA lab. Disinfectants, like other products, are given occasional checks by the states to see if they contain the ingredients named on the label.

He said that if the product seems effective according to the company's tests when it is first registered, and later retains the ingredients named on its label, it should still be effective.

Scientists contend, however, that there is a possibility that the closing of the EPA laboratory may result in accidents of contamination or dilution of some batches.

Whenever the EPA laboratory had found bad batches of the germkilling chemicals, the batches were ordered removed from the market. Now, no such check exists except in Florida, North Carolina and Virginia.

Martha Rhodes, chief of the Florida laboratory that studies the effectiveness of hospital disinfectants and sterilants, said that of the samples they select to test regularly, 30 and 40 percent fail to kill germs and enforcement action must be taken.

Her laboratory is looking for the bad batches and probably finds a higher percentage of them than exists in the marketplace, she said.

Closing the laboratory "is a hell of a way to save money . . . sterilants and disinfectants are things we use in trying to save lives," said Frank B. Engley, professor of microbiology at the University of Missouri. "It looks in this case like we might end up saving money and wasting lives."

Another important effect of closing the laboratory is that it will change the process by which a company can register a new sterilant, the chemicals that had to be certified to kill all germs so they could be used on medical instruments that enter the body during surgery.

The EPA laboratory routinely tested every new sterilant to make sure that it was completely effective.

Now, said one EPA official, sterilants no longer will receive independent testing by the government as a standard procedure. The company's tests will stand as the evidence in favor of the chemicals' effectiveness.

The laboratory being closed is part of an EPA facility in Beltsville.

The part of the laboratory involved in testing disinfectant chemicals has been closed down gradually over the past six months, although the equipment and germ cultures have been kept up so that they could be used again if needed.

Industry officials are concerned over the closing of the laboratory because the action puts the more reputable and conservative companies on the same footing as those willing to make extravagant claims for the effectiveness of their products, since neither is being checked.

In addition, the absence of the EPA laboratory raises the specter of "five, 20, or even 50 states obtaining varying test results on the same product and thereby taking different enforcement actions," said Ralph Engel, president of the Chemical Specialties Manufacturers' Association.

[Reprint from the Washington Post, April 4, 1983]

CUTTING CORNERS AT EPA

While the management is being changed at the Environmental Protection Agency, the evidence of recent poor judgment continues to pile up. Now it develops that the EPA has closed the small laboratory in Beltsville that tested hospital disinfectants. This retreat comes at a time of rising concern about new and tenacious hospital infections.

It is disingenuous of the EPA to say that closing the lab has nothing to do with the budget. The offical explanation is that the people in that lab were needed for other work. No doubt; but they were needed for other work because the Reagan administration has cut the EPA's funds well below the minimum necessary to carry out its responsibilities.

This kind of testing could in theory be carried out by the states, or by the hospitals themselves. But it is hard to think of a more wasteful practice than to have each state, let alone each hospital, do its own tests of these standard compounds. Three states are now doing it, and you will not be reassured to know that one of them reports about a third of the tested samples to be ineffective.

There are fields in which less regulation means greater efficiency. Health care, notoriously, is not one of them. But the departed management of the EPA never seemed to get even as far as that basic point. It never gave any evidence of understanding that its job was the protection of public health. That, fortunately, is a point on which William Ruckelshaus, now returning to the administrator's office, has never needed any instruction.

There are now half a dozen congressional subcommittees examining the recent history of the EPA. One or another of them might usefully ask Mr. Ruckelshaus to take a look at his predecessors' decision to drop the disinfectants from their list of proper public concerns.

UNIVERSITY OF MISSOURI-COLUMBIA,
SCHOOL OF MEDICINE, DEPARTMENT OF MICROBIOLOGY,
Columbia, Mo., May 18, 1981.

Mr. WALTER BARBER,
Assistant Administrator for the Environmental Protection Agency, Washington, D.C.

DEAR MR. BARBER: Recently at meetings of the Association for Advancement of Medical Instrumentation in Washington, as well as meetings in Chicago, I heard that the Environmental Protection Agency was considering the closing of the Pesticide Testing Laboratory in Beltsville, MD. I heard this with considerable disbelief and dismay, and felt that the Agency must not be real serious about this since the only real check and balance that we have on the efficacy of disinfectants for hospitals, nursing homes, and other health care facilities is through this laboratory. Having spent almost 40 years in the area of antimicrobials, and having served on panels for the FDA and as an ad hoc consultant to the EPA some years ago, I have come to the conclusion that since any formulation may be shown to be the best or the worst in its antimicrobial activity depending upon the test methodology, it's extremely important to have a governmental laboratory checking on the claims made by any and all companies. I would hope that such a laboratory is maintained because of its extreme importance to the health care facilities, and to the health of the 35,000,000 who go into hospitals each year, and to the unknown millions who go into the clinics, emergency rooms, and those who are residents of extended care facilities.

Most sincerely yours,

FRANK B. ENGLEY, Jr., PH. D.,
Professor of Microbiology.

COMMONWEALTH OF VIRGINIA,
OFFICE OF THE GOVERNOR,
Richmond, Va., November 27, 1981.

Mrs. ANNE GORSUCH,
Administrator, U.S. Environmental Protection Agency, Washington, D.C.

DEAR MRS. GORSUCH: On behalf of the Virginia Department of Agriculture and Consumer Services and the Virginia Division of Consolidated Laboratory Services, I wish to bring to your attention my concerns regarding the proposed discontinuance of certain programs of the EPA Beltsville Laboratory.

Over the years the staff of that facility has served a vital role to states in pesticide formulation methodology development, pesticide residue testing and efficacy evaluation of health related products such as disinfectants and rodenticides. Generally, the latter is not an integral part of state pesticide regulatory schemes.

Though funding provided through EPA/State Cooperative Pesticide Enforcement Agreements has greatly improved state laboratory capabilities in formulation and residue work, not much has been done to enhance state capabilities in the noted health related product fields. States can conduct analysis of active ingredients in these types of projects. However, bioassay work is critical to testing the efficacy of the products. This is particularly important regarding disinfectants used in hospitals and other health care facilities. While Virginia currently has some disinfectant testing capabilities, our Division of Consolidated Laboratory Services does not do rodenticide efficacy testing. Also, there are numerous areas in which the Beltsville Lab provides invaluable services to state labs and agencies. It has been a ready, central source of information and guidance in questions concerning laboratory techniques and has been especially useful in coordinating the development of new analytical methods.

If the portion of the Beltsville Laboratory is closed as proposed, states may need to redirect cooperative funding resources to make up for the loss of this support service currently provided by EPA. The decreased efficiency overall and the increased costs to states that would result from the proposal are certainly serious enough to merit further discussion about the economic merits of closing an existing and well-run facility versus "gearing up" many state laboratories to do virtually the same job.

Based upon the above thoughts, I would urge you to further evaluate the proposal of discontinuance of biological testing of disinfectants and rodenticides at the Beltsville facility in favor of its continuance.

Sincerely,

MAURICE B. ROWE,
Secretary of Commerce and Resources.

DEPARTMENT OF AGRICULTURE,
AGRICULTURE BUILDING, CAPITOL SQUARE,
Atlanta, Ga., September 9, 1981.

Mrs. ANNE GORSUCH,
Administrator,
U.S. Environmental Protection Agency, Washington, D.C.

DEAR MRS. GORSUCH: Some two or three years ago EPA proposed the closing of the Beltsville Laboratory. This was at the time that States were undertaking State primacy in pesticide use enforcement and when the development and compilation of analytical methodology by this facility was beginning to make it an indispensable source of analytical and technical support to the States. At that time, we pointed out the tremendous contribution that the Beltsville Laboratory was making to the States as a technical repository and methods clearinghouse. Accordingly, EPA and OMB agreed to continue the operation of this facility.

I am now greatly disturbed by news that EPA is proposing to discontinue biological testing of disinfectants and rodenticides at Beltsville. Such a proposal could not possibly be more ill-timed.

States are expanding their programs under State primacy including producer establishment inspections, product surveillance, and use inspection. The use inspection area of enforcement becomes more critical by the day as increasing numbers of facilities for the aged, nursing homes, and other health related institutions are being built.

Disinfectants, rodenticides, bactericides, viricides and other health related products are being developed for this market, where efficacy is of utmost importance. Unfortunately, the efficacy of such health related pesticide products cannot always be confirmed by chemical assay of the formulation. Therefore, we must resort to biological assays to insure that such products are, in fact, capable of accomplishing their label claims.

Since the growth in use of such public health related products has occurred over the last few years, States have not generally developed procedures for testing of these products on a priority basis. However, many States including Georgia, are now establishing new work in the area of biological testing as a part of their outputs under their cooperative enforcement grants from EPA for pesticide use enforcement.

While most of the States possess a rather well defined expertise in chemical testing capability, very few have strong capabilities for biological testing. Protocols for biological assay are vastly different from protocols for chemical testing and require an extremely high degree of experience and expertise for routine performance. The

Beltsville facility has such experience and expertise, developed over a rather long period of work in this area. There is absolutely no other such facility available to the States, which can act as a clearinghouse for biological methodology and provide to the States the biological support they must have if they are to undertake the routine assays of these health related pesticides.

FIFRA provides for the delegation of pesticide use enforcement to the States, and requires that EPA oversee and coordinate State activities, procedures and protocols for accomplishing uniform enforcement practices throughout the nation. The Beltsville facility is absolutely vital to the maintenance of State primacy so far as it impacts on the preservation of public health in this country. As a matter of fact, it would appear that the phasing out of the biological testing program would be a first step in phasing out the entire facility. Such an action would be tantamount to delegating use enforcement to the States and then "pulling the rug out from under us".

I have been serving for a number of years as Chairman of the Plant Industry Committee of NASDA, and as a member of the NASDA-EPA Task Force. Accordingly, I have been closely involved in the development, and implementation of our current pesticide enforcement programs. Therefore, I am most anxious that you take note of the value of biological testing at Beltsville, and that you know of my concern over the present proposal. I am convinced that EPA would be making a tragic mistake if it proceeds with elimination of this testing program.

I strongly urge you to reevaluate this proposal and to maintain this facility for the benefit of both EPA and the States.

With warmest personal regards, I am

Sincerely,

THOMAS T. IRVIN,
Commissioner.

OFFICE OF INDIANA STATE CHEMIST AND SEED COMMISSIONER, DEPARTMENT OF BIOCHEMISTRY, PURDUE UNIVERSITY, AGRICULTURAL EXPERIMENT STATION,
West Lafayette, Ind., September 11, 1981.

Re The Beltsville Laboratories

Dr. JOHN HERNANDEZ,
Associate Administrator,
U.S. Environmental Protection Agency, Washington, D.C.

DEAR DR. HERNANDEZ: We understand consideration is being given to closing these laboratories in response to the overall budgetary reductions now under way in the Federal government. As the administrator of two Indiana pesticide laws, and as the Indiana lead agency in this area, we wanted to add our support to the resolution adopted by the Association of American Pesticide Control Officials at Phoenix last month requesting consideration of alternatives toward continuing these programs.

We have depended totally upon these laboratories for the biological testing of disinfectants and rodenticides for the past ten years. Although our laboratories are well equipped for chemical analyses, we have not developed the skills necessary for the biological testing of these products. This testing requires long experience and expertise which is lacking in most programs, including ours, yet it is essential to continue monitoring these important products.

The Beltsville laboratory is well equipped, the staff has many years experience, and are widely accepted as experts in the field. We are reluctant to see this lost if there are any possible alternatives.

Very truly yours,

E. D. SCHALL, *Commissioner*

NORTH CAROLINA
DEPARTMENT OF AGRICULTURE,
Raleigh, N.C., September 15, 1981.

Dr. JOHN HERNANDEZ,
E.P.A. Deputy Administrator,
Washington, D.C.

DEAR DR. HERNANDEZ: We understand that consideration is being given to the elimination of the microbiological section of the EPA Beltsville, Maryland complex. We are disturbed by this news and urge that it be kept open.

We utilize the Beltsville microbiological section for training, advice, and sample collaboration, and support the continuance of the program at this level.

Sincerely yours,

GEORGE R. WINSTEAD III,
Chemist-In-Charge, Pesticide Lab.

BOARD OF PUBLIC AND SCIENTIFIC AFFAIRS,
AMERICAN SOCIETY FOR MICROBIOLOGY,
Washington, D.C., September 2, 1981.

Dr. ANNE MCGILL GORSUCH,
EPA Administrator, Washington, D.C.

DEAR DR. GORSUCH: The Board of Public and Scientific Affairs and the Committee on Environmental Microbiology of the American Society for Microbiology very much regret that budgetary constraints require the Environmental Protection Agency to terminate people and programs in microbiology. However, the Board and the Committee recognize that the Agency has no alternative at this time but to implement policy established by a new administration which places priority on cost-effectiveness. Neither the Board nor the Committee is in a position to comment on any specific Agency action, but they wish to express concern that decisions to discontinue programs and to reassign personnel in microbiology may prevent fulfillment of the Agency's function of protecting human health and welfare by maintaining environmental quality.

Microbiological laboratories have been an integral part of environmental operations for well over 25 years. They have conducted evaluations of numerous disinfectants and sterilants used in homes and hospitals, they have studied the fate and effects of chemical pollutants of air, soil, and water, and they have contributed to the development of rational alternatives to chemical pesticides.

The information generated by microbiological laboratories within the EPA has been essential to Agency programs of registration and regulation, and Agency microbiologists have served you well as in-house consultants when there was need for expert counsel. Since the Agency can anticipate continuing need for all these functions, it should carefully review plans to terminate microbiological units and to reassign or to discharge personnel associated with those units. Once closed, laboratory operations are difficult and costly to re-establish. The loss to the Agency of its microbiological laboratories could be costly in terms of reliability if not dollars. Before taking any action, the Agency should require convincing evidence that services provided by its own microbiological units can be contracted for at reduced cost and that there will be no decrease in the quality or reliability of the data or information obtained.

Please do not hesitate to let us know if the American Society for Microbiology, its Board of Public and Scientific Affairs or Committee on Environmental Microbiology can assist with the assessment of Agency plans for its microbiological units, or if we can help in any other way. We remain deeply concerned that you continue to understand the importance of microbiology to the realization of the Agency's mission, to protect public health and welfare by maintaining environmental quality.

Sincerely yours,

HARLYN O. HALVORSON, PH. D.,
Chairman, Public & Scientific Affairs Board.
DAVID PRAMER, PH. D.,
Chairman, Committee on Environmental Microbiology.

MISSISSIPPI STATE CHEMICAL LABORATORY,
Mississippi State, Miss., September 14, 1981.

Dr. JOHN HERNANDEZ,
Deputy Administrator, Environmental Protection Agency,
Washington, D.C.

DEAR DR. HERNANDEZ: By way of introduction, I am Dr. James P. Minyard, Jr., State Chemist and Professor of Chemistry at Mississippi State University. I direct the Mississippi State Chemical Laboratory (MSCL), a State Agency and simultaneously a Division of the University. We provide technical advice and product analytical support for Mississippi regulatory programs in pesticides, feeds, fertilizers, foods, petroleum products, and other consumer products.

Jim Buck Ross, Mississippi Commissioner of Agriculture and Commerce, and I are peers; our staffs work jointly on various agricultural product regulatory matters. The Division of Plant Industry, Mississippi Department of Agriculture and Commerce (DPI/MDAC) is our state's lead agency for pesticide programs. Mr. Jack Coley, State Entomologist is Director of DPI/MDAC. Mr. Robert McCarty, Associate Director, supervises the Federal/State Cooperative Pesticide Enforcement Program. MSCL provides technical advice and reports of analytical results on formulations, use dilutions, and environmental residue samples on a sub-contract basis.

A Fellow and Past-Chairman of the Division of Pesticide Chemistry/American Chemical Society, I have been active in regulation and research on insect pheromones, pesticides and toxic substances for the past twenty-three years. Now President-Elect of the Association of Official Analytical Chemists (AOAC), I also chair the Association of American Pesticide Control Officials' (AAPCO) Methods Clearinghouse Committee.

MSCL is quite involved in long-term pesticide research projects. These include investigations on fire ant toxicants, high-technology analytical methods development, and human epidemiology studies funded by EPA/OPP/HED, the "Mississippi Pesticide Hazards Assessment Program (MS/PHAP)", for which I am Project Director. Dr. Earl G. Alley, MSCL's Research Division Director, is scheduled to meet with Dr. Todhunter this week concerning Ferriamicide, a degradable Mirex fire and bait developed in our labs.

This letter is written to offer our support to you and your office in areas where you feel my staff or I could be of service. It is also an appeal for your continued emphasis in EPA of Laboratory support functions provided by various Agency lab units to the state scientists engaged in cooperative Federal/State Pesticide Enforcement Programs.

EPA must retain a solid base of laboratory capabilites for your own investigations in pesticide and toxic substances regulation. Additionally, you should continue to provide (1) training experiences for technical personnel in state labs, (2) high purity pesticide standards for state use in their enforcement programs, (3) QA/QC programs for external monitoring of quality of analytical results (4) analytical methods development and collaborative validation through the AOAC or equivalent mechanism, and (5) other appropriate technical support of state labs engaged in pesticide enforcement, including equipment improvement funds as they are available.

We are concerned about rumors of EPA's consideration of closing certain lab sections in the Beltsville Chemical and Biological Investigations Branch Labs. Biological testing activities of this Beltsville Laboratory are essential to State/Federal programs. CBIB at BARC-E provides tests that many state labs are not presently equipped or staffed with trained personnel to conduct in their own programs. Many such labs send samples to Beltsville for analysis, and to confirm their own chemical and biological tests.

The Beltsville unit has been a major source of pure pesticide reference standards for many years. In 1980-81, I understand they sent 1,100+ standards to 49 states. They cooperated in 27 different projects supporting chemical analyses for states in that same period, and helped improve training for 60 state scientists from 40 different states.

CBIB has led in rodenticide testing for municipal rodent control programs. Very few states are active in this field. The Beltsville group provides back-up to states on hospital disinfectant and sanitizer analyses, and checked bactericidal effectiveness of 97 samples from January-December 1980, plus 48 more in January-August 1981. This work supported regulatory programs of 14 different states in 1980-81, during which time they provided direct technical assistance to the states of North Carolina and Florida.

We are also dismayed at the rumored shift of the Research Triangle Park Unit under Dr. Randall Watts' direction from RTP to Las Vegas. It is counter-productive, we believe, to decrease EPA lab activities and disrupt the quality assurance programs for external monitoring of state performance from RTP. Randys' unit, in ORD rather than OPP, has continued to provide Check Sample Programs to states active in pesticide residue investigations. These provide the external checks necessary for states to insure good QC of analyses on use-dilution and enviromental field investigations. Combining RTP's QA/QC programs with the Beltsville group under OPP, with or without a physical move of personnel and facilities, is logical. Perhaps money could be saved in the process, especially since RTP also provides reference analytical standards to state units and PHAP research units on request.

Finally, Mr. Dean Hill's group at the National Enforcement Investigation Center (NEIC) at Denver has for several years provided excellent training courses for state pesticide chemists, plus Check Sample Programs for external QA/QC of pesticide formulation and use-dilution analyses conducted under cooperative enforcement programs. This complements the AAPCO Check Sample Program, which was run from our Lab for several years, and for which we still provide statistical analyses.

Your and other USA administrators' decisions in program retrenchment, while attempting to maintain essential programs, are very difficult in this time of decreasing resources. Nevertheless, EPA *must* maintain quality federal labs at a viable level to provide the essential technical support capability in pesticides and toxic substances monitoring for all enforcement activities, and to support various Registration Division questions with valid data. Similar changes may be under consideration in other programs associated with toxic substance analyses in environmental samples, but I am not as aware of such program trends as with pesticides.

I am disturbed that EPA is even considering laboratory closures, terminations in technical capabilities, and related cost-reductions in your pesticide action programs. Your Agency and each state faces an ever growing set of complex problems in our mutual efforts to insure safe and responsible use of increasing tonnages of toxic agricultural chemicals. Effective regulation cannot simply be a paperwork exercise, in my opinion.

Pesticide and toxic substances enforcement programs are probably best conducted by state agencies and laboratories. Nevertheless, they must operate under state FIFRA-equivalent laws and regulations which must be enforced uniformly. Effective enforcement must be undergirded by top quality federal laboratories to provide coherent quality nationwide.

Thank you for your careful attention to these matters in making difficult decisions involving EPA Laboratory Programs.

Sincerely yours,

JAMES P. MINYARD, Jr., *State Chemist.*

ASSOCIATION OF AMERICAN PESTICIDE CONTROL OFFICIALS, INC., RESOLUTION ELIMINATION OF BIOASSAYS ON PESTICIDE PRODUCTS

The Environmental Protection Agency is proposing to discontinue, effective October 1, 1981, the bioassay of pesticide products at the Beltsville Laboratory. The continuation of this biological testing is extremely important to many States who are now planning or have only recently initiated work in bioassay under their cooperative enforcement agreements with EPA for State Primacy.

Resolved, that the National Association of State Departments of Agriculture, meeting in Boston, Massachusetts, on September 23, 1981, requests the Administrator of EPA to postpone the elimination or any reduction in bioassays at the Beltsville Laboratory at least until such time as EPA and AAPCO can fully explore the possibility of establishing alternatives to this program.

RESOLUTION No. 2

Whereas, the EPA is proposing to eliminate in the near future the analysis of certain pesticide products and bioassays at the Beltsville Laboratory; and,

Whereas, the AAPCO considers these functions to be important to the State and federal pesticide regulatory programs: Therefore be it

Resolved, that AAPCO requests EPA to enter into discussions with AAPCO to establish possible alternatives toward continuing these programs.

STATEMENT OF EDWIN L. JOHNSON
DIRECTOR, OFFICE OF PESTICIDE PROGRAMS
U.S. ENVIRONMENTAL PROTECTION AGENCY

Good morning, Mr. Chairman and Members of the Subcommittee. I am here today to support a simple reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended. This request for a two year reauthorization without major amendment has been submitted to the Congress as the Administration bill. In accordance with the Chairman's request, my remarks will provide the Subcommittee with a comprehensive overview of the development and current status of the major programs for regulating pesticides in the United States as well as the Agency's proposed budget for pesticide regulatory programs.

As you are aware, this is a time of transition at EPA. Administrator Ruckelshaus has just been sworn in, and will soon have the opportunity to install his own management team and address policy and legislative issues across the board. This is all the more reason for the Congress to approve a simple reauthorization at this time.

Although the past months have been tumultuous ones for EPA, I believe we have accomplishments to be proud of in the pesticides program. Through increased efficiencies in administrative procedures, turnaround times on registration actions have been improved and backlogs of pending actions have been reduced. Guidelines for testing pesticides for health and environmental effects have been published. Important new rules establishing data requirements, improving the registration process, exempting pheromones from regulation, and expanding crop grouping for tolerance setting are nearing completion. Most importantly, protection of public health and the environment has not been sacrificed or compromised during the course of these program improvements and efficiencies.

Pesticides regulation has always been controversial. Given the range and number of important societal interests at stake, scientific uncertainties and the serious consequences for health, the environment, agriculture and property that flow from regulatory actions, there are bound to always be differing viewpoints on how to regulate individual pesticides as well as overall policy objectives. I am gratified that you asked for a comprehensive briefing on the status of the entire pesticide program because, in considering legislation or forming other social policy judgments, it is important to reflect on where we've been, where we are, and where we need to go in future directions. And, sound public policy is more likely to result when all affected interests and government policy makers can base their recommendations and actions on a common information base.

PROGRAM HISTORY AND ACCOMPLISHMENTS

You have asked that I review the history and status of the major program elements in pesticides regulation, discussing trends, accomplishments, and future plans. Figure 1 (attached) is a short history of FIFRA amendments to which the regulatory program has responded through the years.

Looking at the program simplistically, there are two major functions in the Office of Pesticide Programs: registering new chemicals and products and new uses of old chemicals, and reexamining old chemicals to ensure that they meet today's scientific standards.

The building block for both programs is the base of data on the characteristics and effects of pesticides. One of EPA's first chores was to decide what scientific data were needed to make responsible decisions on pesticide products, and what data already existed in Agency files.

DATA REQUIREMENTS

As this Committee is aware, FIFRA was significantly amended in October 1972 to change its emphasis from product performance to human and environmental safety. EPA, through notice and comment rulemaking, developed its first basic set of data requirements in regulations made final in July 1975. Based on the experience gained with these basic requirements over the intervening eight years, EPA most recently proposed much more comprehensive and detailed data requirements in November 1982. These data requirements set forth "what" data will be required to register various types of pesticides for different uses. Detailed Guidelines on "how" to conduct the required studies were printed in February 1983, are available for viewing at state and federal offices, and may be purchased from the National Technical Information Service.

I have attached to my testimony a table which depicts the evolution of data requirements over the past thirty-five years. We have shown data requirements first imposed during the periods 1947-62, 1963-70, 1971-73, and 1974-82 for several major categories: Human Safety, Product Chemistry and Environmental Fate, Fish and Wildlife Effects, Residue Chemistry, and Biorational Pesticides. As you can see, the data requirements have responded to increasingly sophisticated technology in testing and increasing knowledge about potential effects of pesticides.

The data transferred to the Agency when EPA was created in 1970 consisted of many hundreds of boxes of disorganized and often duplicative studies. We estimate that the present data base consists of about one-quarter of a million studies, about 150,000 of which are health and safety studies, and the remainder efficacy studies. We have been working for the past six years on codifying the data and entering it into a new Pesticide Document Management System (PDMS). Using

PDMS, microfiche of the studies can be retrieved very quickly using an automated index to the collection. All chronic health effects studies have now been codified in PDMS. The data conversion process for all studies will be fully completed by September 1984 and will be kept up to data thereafter. In addition to the prime objective of supporting OPP's regulatory programs, improvements in our information systems are enabling us to improve our responses to public requests for pesticide information. We are also working with Purdue University on the development of a National Pesticide Information Retrieval System which will become available through a commercial vendor in October 1983. This system will provide public online access to EPA label information on registered products, as well as selected state registration information.

Let me turn now to the history and accomplishments of our two major program components: registering new uses of pesticides, and reexamining old pesticides.

REGISTERING NEW CHEMICALS, PRODUCTS AND USES

• Registration and Conditional Registration

The system of registering each product individually was developed under the 1947 FIFRA by the U. S. Department of Agriculture (USDA). From 1970 to 1972 EPA continued the USDA practice of routinely registering products without identification and scrutiny of the underlying data, if there already existed a product registered for the same use pattern.

In 1972 Congress amended the FIFRA substantially to provide for a comprehensive regulatory program. The 1972 amendments put an end to the practice of issuing registrations based on "existing use patterns" by providing for compensation to owners of data used by subsequent registrants. In consequence, although registration continued on a product-by-product basis, applicants for registration were required to identify what data supported their products' registrations. EPA was obligated to review the data base identified for each product even though this resulted in multiple reviews of essentially the same data base, since the Agency received many applications for products containing the same active ingredients.

In 1975, EPA issued, as required by the 1972 amendments, final regulations for the registration, reregistration and classification of pesticides. These regulations were essentially a comprehensive statement of data requirements for registration which had been developing during the early '70's in light of modern scientific standards and knowledge of pesticides' acute and chronic effects. However, their promulgation created a "double standard" in registration. Products registered after 1975 had to meet the new, more stringent data requirements of the regulations even though similar or even identical products registered prior to 1975 were generally supported by a much smaller data base. At the time, EPA assumed this inequity would be resolved relatively rapidly by reregistering the pre-1975 products and requiring registrants of such products to upgrade the data base to meet the new requirements. However, by the end of 1976 it became clear for a variety of reasons, (including the revelation that a major independent testing facility, Industrial Biotest Laboratory, had been producing invalid data) that EPA could not accomplish reregistration and eliminate the double standard in a timely fashion. The product registration process came to a virtual halt, since new registrants generally could not meet the data requirements.

Thus, in 1977 the Administration proposed, and in 1978 Congress enacted, major amendments to the FIFRA which relieved the inequities of the existing system. The 1978 amendments permitted conditional registration of new products even though the data base might not fully satisfy data requirements for registration. All registrants of like products would have to provide the missing data at a time specified in the future. Conditional registration serves primarily as a bridge between now and the time all registrants of like products will be required to meet current data requirements.

Conditional registration also freed Agency resources from multiple reviews of the same data and permitted concentration on data review for reregistration. EPA implemented this conditional registration authority early in 1979. In addition, the amendments relieved registrants of products formulated for end-use (actual application to control pests) of the responsibility for submitting most long-term hazard data so long as they used a registered technical grade product to formulate their end-use products. This exemption substantially reduced the burden of data development for small formulators. Finally, the 1978 amendments sanctioned a chemical-by-chemical, rather than product-by-product approach to registration (and reregistration). This registration standard approach will ultimately simplify registration for both the Agency and registrants.

Receipts for registration actions have been increasing considerably in the past few years. For example, the number of new chemical applications has increased over 40% between April of 1983 and April of 1982. This trend may reflect the outcome of industry research and development initiatives of the 70's.

Under the registration program, we plan to conduct next year 250 reviews of new chemical and biorational pesticide applications, 8,500 reviews of old chemical applications, and approximately 7,000 amendments.

° Tolerances

When EPA assumed responsibility for the establishment of pesticide tolerances from the Food and Drug Administration (FDA) in 1970, it adopted the basic scientific procedures initially developed by FDA in the 1950's. Petitioners to the Agency for the establishment of a tolerance submit both chemistry data (to identify residues and to determine at what level residues are likely to occur) and toxicology data (to assess the nature and degree of hazard posed by such residues). The Agency establishes a tolerance only if it can determine that no unreasonable risk will be posed by the expected residues to life-long consumers of the treated food. The Agency reviews and establishes several hundred tolerances per year.

Because of considerable scientific advances in the last 30 years, residue chemistry and toxicology data now required to assess the safety of tolerances are more substantial and sophisticated than were initially required. However, the basic scientific assumptions of the system were not re-examined for nearly 25 years.

In 1975, GAO recommended that EPA, in essence, reassess existing tolerances, since many of these tolerances had been established long before current residue chemistry and toxicology requirements came into being. Before reassessing individual tolerances, EPA began a comprehensive evaluation of the procedures for establishing tolerances in 1977 by requesting the Agency's Science Advisory Board (SAB) to review the procedures and recommend improvements. In 1978, a House Committee issued a report criticizing the tolerance setting procedures and recommending a variety of changes. The Agency referred these recommendations to the SAB for consideration. In May 1979 the SAB issued a final draft report which recommended, among other things, consideration of risks to various subgroups of the general population which may have a greater than average dietary exposure; evaluation of the safety of tolerances as part of total human exposure from many sources besides diet; upgrading of scientific procedures for calculating allowable daily intake of residues; establishment of tolerances for groups of crops rather than individual crops; and completion of data bases which are insufficient by modern standards.

The SAB's recommendations for revising tolerance setting are being pursued. The most significant changes we plan to make are refinement of dietary consumption estimates which go into the calculation of the permissible residue level for each crop, a new crop grouping scheme, and a data call-in program to bring the data base up to today's standards. Individual tolerances are being reassessed as part of the reregistration process.

° Special Registration

- Emergency Exemptions: The 1972 amendments authorized EPA to issue emergency exemptions and the Agency issued final regulations implementing this authority in December 1973. The requesting states submit to EPA information demonstrating that a pest control emergency does exist which cannot be met by the use of federally registered products and information on the emergency control program they are proposing - including the method, rate, area and duration of application of the emergency use pesticide. EPA reviews the risks and benefits of the proposed emergency use in light of available hazard data as well as potential economic or other loss if the pest is not controlled. The final decision depends upon the balance of risks and benefits. Until recently, the Agency received approximately 300-500 emergency use requests per year. In the past two years, the numbers have risen considerably. We have just completed an audit of the emergency exemption program of the past 5 years, which has been made available to the Committee staff, the States and the public. We will be exploring with the States and the public what changes may be necessary in our regulations as a result of the findings of the audit.

- State registration: Until the 1972 amendments, any state could register a pesticide product for use within its borders, regardless of the product's federal status. The 1972 amendments, however, required that all pesticides marketed in the U.S. be federally registered. While states could regulate the sale or use of federally registered products, such regulation could not permit sale or use prohibited by the FIFRA. States could not issue registrations for new uses of products, unless EPA had first certified them as competent to do so and unless there was a special local need for the new use. EPA issued proposed regulations governing state special local need registrations in September 1975 and established an interim state certification program under which a number of states were certified to issue registrations.

In 1978 the state registration provisions of the FIFRA were amended to eliminate the certification requirement so that any state may now issue special local need registrations for additional uses of federally registered products without prior EPA certification. EPA retains the right to disapprove state registrations within ninety days of issuance, but only under very limited circumstances. The Agency promulgated final regulations implementing this new provision of the FIFRA in January 1981. The Agency reviews approximately 1,200-1,700 state registrations per year and to date has agreed with almost all of them.

- Experimental Use Permits: Prior to the 1972 amendments, experimental use permits (EUP's) were issued by EPA and its predecessor, USDA, although the 1947 FIFRA did not explicitly authorize such regulation of experimental uses of pesticides. The 1972 amendments gave EPA explicit authority to regulate the experimental use of pesticides. Final regulations were promulgated in April 1975, specifying when an EUP is necessary, what information must be submitted with an EUP request, and what data reporting requirements must be met during an experimental program. The Agency reviews approximately 200-350 EUP requests per year.

Please refer to Figures 2 and 3 for an illustration of the numbers of outputs over time in reviewing new registrations activities. The bar graphs in Figure 2 will demonstrate how many reviews the Agency conducts, which is not the same as the number of registrations approved. It usually takes several review cycles to complete an action, and not all reviews result in approvals. The number of actual uses approved is demonstrated by the broken line within the bar graphs. Turnaround times for the primary registration reviews for the past three years are depicted in Figure 3. As these charts illustrate, we have improved our processing times over the past several years.

REVIEW OF "OLD" CHEMICALS

° Special Review

When Congress amended FIFRA in 1972, it required EPA to undertake a monumental task: to review all chemicals already on the market and reregister them against today's scientific standards.

This has not been an easy task. The Agency has pursued a deliberate long-term strategy for reviewing these old chemicals, dealing first with identified problems, obtaining new data on chemicals with inadequate data, and curtailing uses, changing labels, and/or reaffirming as appropriate, previously approved uses of existing chemicals.

In beginning this task, we were faced with a universe of about 1400 active ingredients used in approximately 50,000 registered products. The 1400 active ingredients actually consist of about 600 groups of closely related active ingredients.

So, as indicated in Figure 4, we first identified the problem chemicals and put them in a special review process (89 chemicals have been dealt with in a special way); the remaining chemicals are designated for registration standards review.

Initially the Agency exercised this new authority granted by the 1972 amendments under §6 of the Act by issuing notices of intent to cancel registrations of pesticides which apparently did not meet the statutory standard. Such notices resulted in lengthy, formal adjudicatory proceedings, where risk and benefit evidence was presented in trial-like hearings.

In July 1975, the Agency issued its final regulations governing registration, reregistration and classification of pesticides under FIFRA §3. These regulations established criteria for identifying what pesticide effects the Agency would presume to be unreasonable -- effects such as cancer, birth defects, mutagenic effects. The presumption could be rebutted by showing that the effects data were not valid, the risks could be reduced, or the benefits exceeded the risks. The process was thus called rebuttable presumption against registration or RPAR.

Originally the RPAR process was primarily a means to quickly identify pesticides for which the formal adjudicatory hearings under §6 should be initiated. Development of risk and benefit data would still occur chiefly during the hearings. However, shortly after the regulations were issued, both Agency initiatives and Congressional amendments in November 1975 radically altered the RPAR process. An ad hoc committee directed by the Administrator determined that reliance on formal hearing procedures imposed costly burdens on both Agency and industry and also discouraged participation by interested parties in the decision-making process. The Congressional amendments required the Agency to submit its proposed decisions to a review by the then newly established Scientific Advisory Panel and by USDA. These reviews could only be meaningful if both risk and benefit assessments had already been developed as part of the Agency proposed decision. In addition, one of the 1978 amendments specified that RPAR's be initiated only on the basis of validated tests or other significant evidence raising prudent concerns of unreasonable adverse risk to man or the environment.

Thus since the RPAR process became operational in early 1976, it has been, in fact, an informal and thorough review process for both risk and benefit information on a pesticide which meets or exceeds the RPAR risk criteria. It results in a regulatory decision prior to any hearing. Hearings are used to challenge and test the validity of Agency decisions. The process has proven to be an equitable and effective, though sadly not much faster, alternative to the earlier exclusive reliance on formal hearings.

Figure 5 shows the progress of RPAR's and provides a synopsis of the outcomes of the special review process (special review includes §6 cancellations and suspensions, final RPAR resolutions, negotiated settlements, and voluntary cancellations).

The top chart on Figure 5 shows actual RPAR's issued. We began RPAR's on the bulk of the chemicals in the early years of the RPAR program, and are now finishing up the actions begun in 1977, '78 and '79. One of the first steps in RPAR was not only to identify the potential problems, but to rank them in order of greatest risk based on the severity of the suspected health effects and dimensions of exposure to the population (food use chemicals, because of their wide exposure to the general population would rank higher than an industrial use chemical for example). Thus our approach was to tackle the potentially most significant problems first.

The top chart also illustrates why there were many more RPAR's issued several years ago than there are now. The fact of the matter is that EPA has achieved much of its original purpose by dealing with most of those older existing pesticide registrations that were identified as potentially posing an unreasonable risk. The newer pesticide registrations, having fuller, more recently developed data bases, are less likely to give rise to an RPAR proceeding. Therefore it would be very unusual -- and in fact an indication of flaws in the process -- if the numbers of RPAR's initiated continued to be high, since the process is designed to correct the errors or problems of the past Additional RPAR candidates are, of course, expected to emerge from the now ongoing data-generating efforts being required of registrants of existing chemicals with incomplete data bases. However, I think it is important to realize that the Agency is coming to an end of a most significant first major step in catching up with and reviewing 25 years accumulation of previous pesticide decisions as directed by Congress.

The accomplishments of this era go a long way in terms of public health protection to meeting the 1972 Congressional mandate to review old chemicals. The lower chart on Figure 5 depicts the outcomes of the special review process. I believe this chart demonstrates EPA's attempt to be even-handed in coming to grips with potential problem pesticides, recognizing both risks and benefits. A number of pesticides have come off the market, many voluntarily, as a result of the regulatory program. But many decisions have resulted in some uses being cancelled while others are retained under more stringent use restrictions. Still others have been dealt with by imposing restrictions across the board to reduce risks to acceptable levels. In some RPAR's we have found the data base to be so inconclusive that the primary action is to require the generation of data to answer the questions in an informed way. Still others are found to require only minor changes because the review concluded that the existing uses do not pose unreasonable adverse effects, taking into account actual and/or potential exposure.

I am often asked why the trend in recent years seems to be to allow continued registration of chemicals rather than to cancel or initiate an RPAR on them. Many of the chemicals returned to the registration process in the last two years are ones identified in 1975 but which the early reviews indicated to be of less potential risk than other chemicals on the RPAR list. As I said before, a decision was made early in the process to deal first generally with the chemicals that appeared to pose greater risks and on which we had more data indicating problems of risk.

As we completed our efforts with those higher priority chemicals during the late 1970's, we were able to turn to these lower priority chemicals in the early 1980's. It is therefore reasonable that many of these chemicals have retained their registrations with certain important "strings" attached, e.g., additional use and exposure restrictions, cancellation of certain uses or types of formulations or applications, additional data requirements, and so forth. The increased understanding of the RPAR process by the regulated industry, and their increased understanding of the need for and willingness to accept restrictions on the uses of their chemicals rather than battling for years over the outcome, has facilitated many of these resolutions, as has the introduction of better tested, more effective alternatives to older pesticides.

With the conclusion of the review of the original suspect chemicals in sight, the Special Review process is now being integrated into Registration Standards reviews, since the need for special action will be primarily identified in the future by data reviews and data generation in the latter program. The Agency has stated publicly that changes are needed to the regulations governing special reviews in order to bring the rules into compliance with the 1978 amendments to FIFRA, to speed the time it takes to complete an intensive review, and to reduce the costs to the Government and other participants. We believe that a greater level of protection is accorded the public when we are able to reach the earliest possible conclusion to questions of a product's potential risk. We hope to have proposed regulations out for public comment by the end of the calendar year.

- Registration Standards

The second major effort is to review the remainder of old chemicals which have not been singled out as potential problems or as especially risky in the Registration Standards program. Reregistration has progressed by fits and starts. The original scheme for reregistration in the early 70's assumed that most data on file were valid and properly reviewed and that any problems with the data had previously been identified and resolved. Thus the Agency review of data on hand had focused on identifying data gaps, not on validating the existing data. However, in 1976, discussions with FDA and GAO, Senate hearings, and the Agency's own internal operations review raised serious questions about the adequacy of test data in EPA files and the completeness of the Agency's own review and follow-up. In consequence, reregistration was halted so that the Agency could re-examine its planning assumptions and restructure its reregistration strategy.

To deal with this massive data review problem, the

Administration proposed a new, more efficient method of review to Congress in 1977. This approach, sanctioned in the 1978 amendments to the FIFRA, allows the Agency to make one comprehensive review and decision per pesticide active ingredient rather than multiple individual decisions for the many products containing the active ingredient. The 1978 amendments also authorized the Agency to waive review of efficacy data. This new authority has enabled the Agency to concentrate resources on the review of potential risks to man and the environment, and thereby substantially shorten the length of time necessary to accomplish reregistration.

The current approach results in the development of a Registration Standard for a pesticide chemical which sets forth the conditions for reregistration of old products and registration of new products. The processing of registration applications involves a straight-forward decision whether the conditions of the Standard have been met. To date, approximately 50 standards have been issued with about 20 more expected by the end of calendar year 1983. The Agency is using a cluster approach to the development of standards so that chemicals with like uses are reviewed at the same time. Clusters have been ranked so that high volume and food use pesticides are addressed sooner rather than later, although some of the early standards were developed on small volume chemicals, selected principally to develop and test the process.

Even though there are 600 chemical groups, this does not mean that we need to develop 600 registration standards. We estimate that approximately half will not require standards because they are out of production or will be voluntarily withdrawn rather than develop new data, or are natural substances not requiring review. Assuming the planned rate of standard development of 35 per year beginning in FY 84, standards will be developed for all active ingredients by the end of FY 1991.

- Extent of data base

One of the key questions in doing a Registration Standard is whether the chemical in question has an up-to-date data base by today's standards. We estimate that for most chemicals registered prior to the 1975 data requirements the answer is "no." This is not to impugn pesticide registrants -- it is primarily a reflection of the fact that data requirements have increased over time and many products were registered in earlier years when fewer requirements were in place. EPA has discovered, not surprisingly, that the early registration standards have resulted in many data-generating requirements.

In order to obtain important data before the Agency completes or even begins a Registration Standard on a chemical, we have initiated a Data Call-In program. Letters are being sent to registrants identifying long term chronic testing needs (cancer, chronic feeding, reproduction and teratogenicity testing) and requiring the initiation of these important studies. Since long-term cancer studies take approximately four years to complete, including the start-up and analysis phases of the studies, it will take several years before necessary data comes in on a particular chemical prior to the registration standard review. We anticipate that in 1985 we will begin developing standards with data generated by the data call-in program.

Figure 6 shows the progress of Data Call-In. 120 chemicals have been covered by data call-in to date. By 1985, we will have requested testing on chemicals representing 90% of pesticides used in the U.S. By 1988, we will have covered the remaining 10%. Figure 7 is a flow diagram of the registration standards process, showing the interfaces with data call-in and special reviews.

- Quality of data base

Review of data for registration standards also focuses on the quality of the studies in our files. Data gaps occur not only where data just doesn't exist, but also where data exists but is invalid or inadequate.

The scandal associated with Industrial Biotest Laboratories (IBT) shook both the industry and the public. It underscores the need for scrutiny of old studies, and for constant vigilance in reviewing incoming information.

In response to the IBT situation, EPA and FDA initiated joint Laboratory Audit Program. Under this program, FDA inspectors ensure that the lab is in compliance with Good Laboratory Practices; EPA personnel audit raw data from actual studies performed in the lab. Between one and two hundred inspections of laboratories developing health and safety data on pesticides have taken place under this program since 1977, and we plan to conduct Good Laboratory Practice inspections and/or data audits on some 60 laboratories in FY 84. EPA developed a procedure for handling laboratory audits in the Agency in March 1982, and has most recently (April 1, 1983) defined the process in greater detail. These documents are publicly available.

Concerning the impact of IBT on the overall data base, there are approximately 1200 studies on pesticides conducted by IBT. The governments of the U.S. and Canada have cooperated in the lengthy task of reviewing all these studies to determine their validity. The validation process is now complete, and has revealed that over two-thirds of the long-term IBT studies are invalid. The next step, which we plan to complete by mid-June, is to determine how much of the data base on any particular chemical is represented by these invalid studies; and whether there are replacement studies or other studies on that chemical performed by another laboratory which can be used to assess the registration in spite of the IBT studies. We will be sharing this information with the Congress and the public very shortly.

- Status of Largest Use Pesticides

There are many numbers you can use in describing the status of the review of old chemicals. As I said earlier, there are over 300 chemicals now in or scheduled for Data Call-In and Registration Standards. That is a large number. But I think the real measure of progress is whether we are addressing the chemicals to which the public is really exposed.

Figure 8 shows that much of the chemical use market is actually represented by under 70 chemicals, not including the disinfectants industry. Twenty-five insecticides represent 83% of the market; 32 herbicides represent 82% of the market; and 8 fungicides represent 71% of the market. As the pie-charts demonstrate, the Agency is dealing with these high-volume chemicals in an aggressive way. Almost all either 1) have been through or are going through the special review process, (cancellation, suspension, RPAR, or voluntary cancellation) 2) have been through or are actively going through the registration standards process, or 3) have been subject of data call-in letters. So, while we have many standards to go, we are putting our resources and our emphasis on those old chemicals that matter most in terms of exposure to the general population.

RESOURCES

That completes my overview of our critical Program outputs. I will now turn to the history of our resources over the past six years years beginning in 1978, and including projections for our proposed FY 1984 budget.

Expenditures

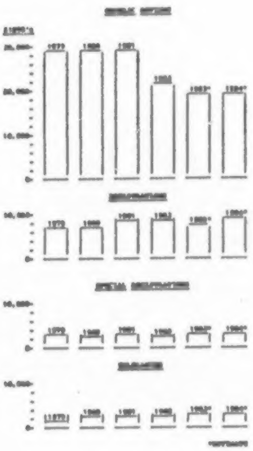

FIG. 9

Full Time Equivalents

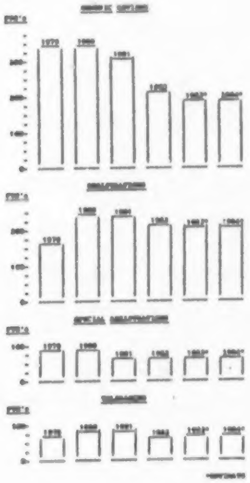

FIG. 10

Figure 9 shows our resources in terms of dollars; Figure 10 shows Full-Time Equivalents, or workforce. We have stabilized resources in FY 83 and FY 84 which will give us a better ability to plan and pace our work outputs.

These charts depict our Decision Units in the budget process. We have sought and achieved many improvements in efficiency in our adminsitrative processes. I emphasize here that we have sought to respond to the workload by concentrating on management and administrative improvements, and not by shorting scientific review. We have, in fact, sought to protect our scientific resources above all other categories of personnel. Should the Program receive additional resources in the future, our first priority will be to gain additional scientific staff. It is my opinion that we have made all gains in administrative efficiency that we can. The next area of improvement will be in data organization and management.

COURT CASES

Before turning to the specifics of the FY 1984 budget, I would briefly mention that during the last year, there have been court rulings in three lawsuits concerning primarily the data compensation provisions of §3 of FIFRA which may affect the Agency's ability to register pesticides (Mobay vs. Gorsuch, NACA and Ciba-Geigy vs. EPA, and Monsanto vs. Acting Administrator). The most recent case brought by Monsanto Company resulted in a District Court ruling in April that certain sections of FIFRA §3 and 10 were unconstitutional.

The potential impact of these suits on the operation of the program is obviously significant. However, before considering legislative changes, I believe we should let the legal process play out to its final conclusion. We believe that we can address the issues of cite-all, which were the subject of the first two law suits, through revised notice and comment rulemaking. "Cite-all," as you may recall, is shorthand for EPA's requirement that registrants cite all relevant data in EPA files in support of their applications. The Agency has solicited public comment on alternatives to the regulations requiring cite-all, and we hope to have final regulations in place by the end of the calendar year. In addition, we have a draft interim procedure developed to address the cite-all issue between now and the promulgation of final regulations which could be put in place if the impediments presented in the Monsanto case are resolved soon.

Regarding the constitutional issues raised in the District Court ruling on the Monsanto case, the Government has appealed the judgment to the Supreme Court, and plans to request a stay pending the resolution of the case on the merits. Other courts have ruled in the Government's favor on these constitutional issues in the past several years. It is not likely that the Supreme Court would rule on the merits until sometime next year. It is the Agency's opinion that changing the legislation before the issues have been resolved in the high court would be premature.

FY 1984 BUDGET

Having provided that broad overview, let me now turn to the proposed budget for FY 84. For budgetary purposes the non-research activities fall into three categories:
1) Registration, Special Registration and Tolerances;
2) Generic Chemical Review and Special Review; and
3) Pesticides Enforcement.

Given the need for continuing fiscal restraint, the pesticide regulatory program has established priorities and planned activities carefully, to ensure that the Agency's health and safety responsibilities in pesticide regulation will be met.

The Administration's proposed FY-84 budget for total pesticide program activities is $52,742,600. This amount is $185,500 less than the level of funding for the current FY-83. The reduction occurs primarily in the area of enforcement grants to the States, reflecting a continuing shift of responsibility from Federal to State enforcement which was begun in the mid-seventies and given impetus by the 1978 amendments.

Of the total budget proposal, $46,680,000 is for non-research pesticide activities. Of this amount, $46,624,400 is requested for authorization under the FIFRA and $55,600 under the National Environmental Policy Act. $6,062,600 of the total budget proposal is for research and development activities. However, since the Agency has requested extension of its research and development authorities under a different bill, I will confine my discussion primarily to non-research pesticide activities.

In developing the FY-84 budget, we have continued to keep in mind certain basic priorities:

- the need to protect the public and pesticide applicators from unreasonable risks which may be associated with the use of specific pesticides;
- the need to foster improved understanding and cooperation among pesticide manufacturers, pesticide users, and the Federal and State governments in order to more effectively and efficiently achieve the goals of FIFRA;
- the need to improve the quality of the available information on which the Agency bases its decisions and policies;
- the need to carry out our various responsibilities efficiently in terms of both our own resource expenditures and possible impacts on pesticide producers and users.

REGISTRATION, SPECIAL REGISTRATION AND TOLERANCES

The Agency's goal in conducting these activities is to facilitate a steady flow to the marketplace of pesticide products posing no "unreasonable adverse effects" to man or the environment, taking into account the economic, social and environmental costs and benefits of these product uses.

Under this part of the pesticide program, EPA registers new pesticide products and uses, giving special consideration to: 1) new chemicals offering an extra measure of environmental protection; 2) alternatives to pesticides which have been cancelled or which pose or suggest serious threats to the environment; and 3) minor uses of pesticides for which grower needs are great but economic incentives to manufacturers are low. Through this program, EPA also accomplishes routine registration and amended registration actions, issues special registrations including emergency exemptions and experimental use permits, reviews State special local needs registrations, and establishes pesticide residue tolerances.

Our FY-84 budget request for this program is $14,199,100. This level of funding represents an increase of $1,966,600 due chiefly to the increased cost of personnel payrolls (that is, to fund personnel compensation and benefits). Workyears involved will not change from FY-83.

As stated earlier, under the registration program, we expect to conduct 250 reviews of new chemical and biorational pesticide applications, 8,500 reviews of old chemical applications, and approximately 7,000 amended registrations.

Regarding special registrations in FY-84, EPA will be funded to conduct 770 emergency exemption reviews, 475 experimental use permit reviews, 100 State experimental use permit reviews, 175 temporary tolerance reviews, and will conduct reviews of 1,100 State special local needs registrations. In the tolerance area, the Agency will be able to conduct 640 tolerance petition actions and 50 inert ingredient reviews next fiscal year.

In summary, the high level of production achieved by EPA in the pesticide registration program in FY-83 will be maintained during FY-84.

GENERIC CHEMICAL REVIEW AND SPECIAL REVIEW

The Generic Chemical Review program consolidates resources and consists of decision processes from the previous Registration Standards and RPAR Review programs, and includes the laboratory audit program. The objectives of program generic review, as discussed earlier, are to reregister currently registered pesticides, to provide a more sound basis for registering new pesticides, and to evaluate potentially hazardous pesticides.

Our FY-84 budget request for the Generic Chemical Review program is $19,342,100. This level of funding represents a decrease of $299,000 and 1.5 permanent workyears from FY-83. While Salaries and Expenses will increase by $701,000, Abatement, Control and Compliance fundings will decrease by $1,000,000. This decrease represents a reprogramming of extramural funds to cover increases in the Salary and Expense accounts in the Generic Chemical Review program and in Registration, Special Registration, and Tolerances.

These resources will permit the completion of 10 Special Review decisions. We anticipate that 35 registration standards, up 59 percent from FY-83, will be established. We plan to conduct Good Laboratory Inspections and/or data audits on some 60 laboratories in FY-84, roughly a thirty percent increase over FY-83. The staffing of the laboratory audit program will also increase by approximately one-third in FY-84. The Agency will continue to implement the data call-in program to ensure that long-term health effects data for identified chemicals will be available by the time standards development begins. Use of the cluster concept and ranking strategy will also continue in 1984, to ensure early review of clusters with high volume production and high exposure for the general population.

PESTICIDES ENFORCEMENT

The Pesticide Enforcement program monitors pesticide producers, distributors and users for compliance with the FIFRA, and provides compliance assistance to the regulated community. Figure 11 depicts enforcement actions at the Federal and State levels over the past five years. Where compliance cannot first be obtained through other means, the Agency's enforcement program prepares and issues notices of violation and administrative orders. In accordance with Congressional intent, much of the Agency's enforcement program is conducted by cooperating State agencies through Federal/State Cooperative Enforcement Agreements. As the chart makes clear, the decline in Federal inspections has been balanced by a corresponding increase in State activities. The Pesticides Enforcement program within EPA manages and funds these cooperative agreements with the States, as well as State applicator certification and training programs.

For FY-84, the funding request for the Pesticides Enforcement program is $13,138,800, a decrease of $1,395,000 from FY-83. This overall reduction in funding reflects a continuing shift in emphasis from Federal to State enforcement. The principal reduction in dollars is in the area of enforcement grants to the States. As part of the cooperative enforcement agreements, States and Territories will determine their own local enforcement priorities, and will target their enforcement resources to act upon these priorites and demonstrated problems. We do not believe, therefore, that the reductions will prevent the States from conducting effective pesticide enforcement programs.

At the planned level of funding, the Pesticides Enforcement program at EPA Headquarters will continue to exercise its primary role in program management, oversight and training, cooperating closely with the States. In addition, Headquarters will provide support to the FIFRA regulatory development and review process, and will manage and execute national programs to monitor compliance with FIFRA regulatory actions, such as our 1983 toxaphene cancellation order and the child resistant packaging rules.

The Regional Offices will continue to negotiate and manage grants for the cooperative enforcement programs and the certification programs. To date there are 52 participating

States and Territories in the cooperative enforcement program. Compliance monitoring activities under the State cooperative agreements will include pesticide producer establishment and marketplace inspections, use and reentry investigations, import inspections, applicator license and record inspections, and dealer record inspections.

The Pesticide Certification and Training program will support 51 applicator certification and 52 training programs in States and Territories, and a Federally run program in Nebraska. An increase of $100,000 is provided for the certification program in Colorado, which will be conducted by the State for the first time in FY-84. The States will be encouraged to raise or implement fees to increasingly support the certification programs.

In addition to these Abatement, Control and Compliance activities, the Agency is also requesting funding of $6,062,600 for pesticide research and development activities under the reauthorization of the Environmental Research, Development, and Demonstration Authorization Act.

I would also like to add at this point that we are requesting, in addition to a simple reauthorization of the FIFRA, a five year extension of the activities of the Scientific Advisory Panel (SAP), which will authorize its important peer review function until September 30, 1988.

As you know, FIFRA requires that all proposed and final regulations issued under section 25(a) and proposed cancellations or changes in the classification of pesticides be reviewed by the SAP for their impact on health and the environment. Since its creation by Congress in 1975, the SAP had always been reauthorized prior to its expiration. However, the last session of Congress did not pass amendments to FIFRA which would have reauthorized the SAP. As a result, the Committee terminated on September 30, 1981.

Reestablishment of the SAP is essential to the Agency's implementation of FIFRA. The Panel's absence results in a shortfall of outside expert scientific advice to the Agency on pesticide regulatory issues affecting public health and the environment.

New Panel members have been chosen from nominations by the National Institutes of Health and the National Science Foundation, in accordance with Section 25(d) of FIFRA. We have just revived the SAP for one year through the Federal Advisory Committee Act. However, this is just a temporary measure until a more long-term reauthorization under FIFRA can be effected. Therefore, prompt action on your part to reauthorize the SAP will be appreciated.

In conclusion, we are confident that our authorization request of $46,624,400 for non-research pesticide activities will be sufficient to maintain a pesticide regulatory program which both protects public health and the environment and also permits the timely introduction of new pesticides to meet the pest control needs of agriculture, industry, and the home and garden.

I hope this overview and discussion of the budget has been helpful to your Committee. I would be pleased to answer any questions you may have.

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED

DATA REQUIREMENT	DATE ESTABLISHED			
ENVIRONMENTAL - Fish and Wildlife	1947-62	63-70	71-73	74-82
1. Fish (2 species), Acute LC_{50}		X		
2. Bird (2 species, Acute Oral LD_{50}		X		X (1 species)
3. Crustacean, Acute (Daphnia, shrimp)		X		
4. Mollusc, Acute		X		
5. Marine vertebrate (1 fish)				X
6. Simulated Field Testing - Birds and mammals		X		[Now included under 8(a)]
7. Bird (2 species), Subacute Feeding			X	
8. Special Testing				
(a) Field monitoring of effects on wildlife populations		X		
(b) Aquatic ecosystem (laboratory)			X	[deleted]
(c) Aquatic invertebrates (laboratory)			X	
(d) Other			X	
9. Reproduction Studies - Fish, birds, mammals			X	
10. Residue - Fish, birds, mammals		X		

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED			
PLANT PROTECTION	1947-62	63-70	71-73	74-82
1. Target area phytotoxicity*				X
NONTARGET AREA PHYTOTOXICITY				
Tier 1:				
2. Seed germination/seedling emergence				X
3. Vegetative vigor				X
4. Aquatic plant growth				X
Tier II:				
5. Seed germination/seedling emergence				X
6. Vegetative vigor				X
7. Aquatic plant growth				X
Tier III:				
8. Terrestrial field				X
9. Aquatic field				X

*These data requirements are generally waived.

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED			
NONTARGET INSECTS	1947-62	63-70	71-73	74-82
NONTARGET INSECT TESTING-POLLINATORS				
1. Honey bee acute contact LD_{50}				X
2. Honey bee-toxicity of residues on foliage.				X
3. Wild bees important in alfalfa pollination-toxicity of residues on foliage.				X
4. Honey bee subacute feeding study				[Reserved]
5. Field testing for pollinators....				X
NONTARGET INSECT TESTING-AQUATIC INSECTS				
6. Acute toxicity to aquatic insects				[Reserved]
7. Aquatic insect life-cycle study.				[Reserved]
8. Simulated or actual field testing for aquatic insects.				[Reserved]
9. Nontarget insect testing-predators and parasites.				[Reserved]

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES
AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED			
PRODUCT CHEMISTRY AND ENVIRONMENTAL FATE	1947-62	63-70	71-73	74-82
1. Chemical and physical properties (Such as solubility, vapor pressure, flash point)	X			
2. Product identity: identity of ingredients........	X			
3. Statement of composition.........	X			
4. Discussion of formation of ingredients....................				X
ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS:				
5. Preliminary analysis.............				X
6. Certification of limits..........				X
7. Analytical methods for enforcement of limits...........	X			
8. Submittal of samples.............	X			
9. DEGRADATION STUDIES				
Hydrolysis		X		
Photolysis in water		X		
Photolysis in soil		X		
Photolysis in air				X

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED			
PRODUCT CHEMISTRY AND ENVIRONMENTAL FATE (Continued)	1947-62	63-70	71-73	74-82
10. MOBILITY STUDIES				
Runoff		X		
Leaching		X		
Volatility (lab and field)				X
11. METABOLISM STUDIES				
Aerobic soil..................			X	
Anaerobic soil................			X	
Anaerobic aquatic.............				X
Aerobic aquatic...............				X
Activated Sludge..............				[Reserved]
Effects on Microbes...........		X		[Reserved]
Effects by Microbes...........		X		[Reserved]

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES
AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED			
PRODUCT CHEMISTRY AND ENVIRONMENTAL FATE (Continued)	1947-62	63-70	71-73	74-82
12. DISSIPATION STUDIES-FIELD				
Soil		X		
Aquatic (sediment)			X	
Forestry				X
Combination and tank mixes				[Generally not required]
Soil, long-term				X
13. ACCUMULATION STUDIES				
Rotational crops:				
(Confined)		X		
(Field)		X		
Irrigated crops				X
Aquatic non-target				X
Fish		X		

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES
AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED		
HUMAN SAFETY TESTING	1950-59	60-69	70-82
ACUTE TESTING			
Oral LD_{50} - rats..................	X		
Dermal LD_{50} -....................	X		
Inhalation LC_{50} - rat............	X		
Primary eye irritation-rabbit.....	X		
Primary dermal irritation.........	X		
Dermal sensitization..............	X (limited)	X	
Acute delayed: Neurotoxicity-hen.	X		
SUBCHRONIC TESTING			
90-day feeding-rodent, nonrodent.	X (Rat)	X (Rat & dog)	
21-day dermal.....................	X		
90-day dermal.....................	X		
90-day inhalation-rat.............			X
90-day neurotoxicity..............			X

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES
AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED		
HUMAN SAFETY TESTING	1950-59	60-69	70-82
CHRONIC TESTING			
Chronic feeding-2 spp. rodent and nonrodent............	X*		X**
Oncogenicity study-2 spp..........			X
Teratogenicity-2 species..........		X (1 sp)	X (2 spp)
Reproduction-2 generation.........		X (3 generation)	X (2 generation)
MUTAGENICITY TESTING			
Gene mutation.....................			X
Structural chromosomal aberration.			X
Other mechanisms of mutagenicity..			X
SPECIAL TESTING			
General metabolism................		X	
Domestic Animal Safety............			X

* 2 year rat and 2 year dog studies.
**2 year rats and 1 year dog studies.

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES
AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED			
REENTRY PROTECTION	1947-62	63-70	71-73	74-82
Foliar dissipation................				X
Soil dissipation..................				X
Dermal exposure...................				X
Inhalation exposure...............				X

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES
AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED			
RESIDUE CHEMISTRY	1947-62	63-70	71-73	74-82
Chemical identity.................	X			
Directions for use................	X			
Nature of the residue plants				
Livestock.........................	X			
Residue analytical method.........	X	(X poultry)		
Magnitude of the residue:				
Crop field trials.................	X			
Processed food/feed...............		X		
Meat/milk/poultry/eggs............	X	(X poultry)		
Potable water.....................		X		
Fish..............................		X		
Irrigated crops...................		X		
Food handling.....................		X		
Reduction of residue..............		X		
Proposed tolerance................		X		
Reasonable grounds in support of the petition.......................		X		

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED			
BIORATIONAL PESTICIDES: PRODUCT ANALYSIS	1947-62	63-70	71-73	74-82
Product analysis................				
Manufacturing process...........				1981*
Discussion of formulation of unintentional ingredients..				
Analysis of limits..............				
Certification of limits.........				
Analytical methods..............				
Physical and chemical properties....................				
Submittal of samples............				
RESIDUE ANALYSIS				
Biochemical agents:				
Chemical identity.............				
Directions for use............				
Nature of the residue...........				
Plants........................				
Livestock.....................				
Residue analytical method.......				V

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*Prior to 1981, biorational pesticides (microbials, biochemicals), were subject to the same data requirements as conventional pesticides on a case-by-case basis.

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED			
BIORATIONAL PESTICIDES: RESIDUE ANALYSIS (Continued)	1947-62	63-70	71-73	74-82
Magnitude of the residues:				1981*
Crop field trials				
Processed food/feed				
Meat/milk/poultry/eggs				
Potable water				
Fish				
Irrigated crops				
Food handling				
Reduction of residue				
Proposed tolerance				
Reasonable grounds in support of the petition.				
Microbial agents				

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*Prior to 1981, biorational pesticides (microbials, biochemicals), were subject to the same data requirements as conventional pesticides on a case-by-case basis.

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED			
BIORATIONAL PESTICIDES: TOXICOLOGY	1947-62	63-70	71-73	74-82
TOXICOLOGY: Biochemical agents				
Tier 1:				
Acute oral....................				1981*
Acute dermal...................				
Acute inhalation................				
Primary eye irritation..........				
Primary dermal irritation.......				
Hypersensitivity study..........				
Hypersensitivity incidents......				
Studies to detect genotoxicity..				
Cellular immune response........				
Tier II:				
Mammalian mutagenicity tests				
Subchronic oral.................				
Subchronic dermal...............				
Subchronic inhalation...........				
Teratogenicity..................				
Cellular immune response........				
Tier III:				
Chronic exposure................				
Oncogenicity....................				

*Prior to 1981, biorational pesticides (microbials, biochemicals), were subject to the same data requirements as conventional pesticides on a case-by-case basis.

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED			
BIORATIONAL PESTICIDES: TOXICOLOGY (Continued)	1947-62	63-70	71-73	74-82
TOXICOLOGY: Microbial agents				
Tier 1:				1981*
Acute oral				
Acute dermal				
Acute inhalation				
I.V., I.C., I.P. injection				
Primary dermal				
Primary eye				
Hypersensitivity study				
Hypersensitivity incidents				
Cellular immune response				
Tissue culture				
Tier II:				
Acute oral				
Acute inhalation				
Subchronic oral				
Acute I.P., I.C				
Primary dermal				
Primary eye				
Cellular immune response				
Teratogenicity				
Virulence enhancement				
Mammalian mutagenicity				V

*Prior to 1981, biorational pesticides (microbials, biochemicals), were subject to the same data requirements as conventional pesticides on a case-by-case basis.

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED			
BIORATIONAL PESTICIDES (Continued)	1947-62	63-70	71-73	74-82
Tier III:				1981*
Chronic feeding				
Oncogenicity				
Mutagenicity				
Teratogenicity				
NONTARGET ORGANISM AND ENVIRONMENTAL FATE: Biochemicals.				
Tier 1:				
Avian acute oral				
Avian dietary				
Freshwater fish LC_{50}				
Freshwater invertebrate LC_{50}				
Plant studies				
Nontarget insect testing				
Tier II:				
Volatity				
Dispenser-water leaching				
Adsorption-desorption				
Octanol/water partition				
U.V. absorption				
Hydrolysis				
Aerobic soil metabolism				
Aerobic aquatic metabolism				
Soil photolysis				
Aquatic photolysis				V

Prior to 1981, biorational pesticides (microbials, biochemicals), were subject to the same data requirements as conventional pesticides on a case-by-case basis.

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES
AND DATE ESTABLISHED (Continued)

DATA REQUIREMENTS	DATE ESTABLISHED			
BIORATIONAL PESTICIDES (Continued)	1947-62	63-70	71-73	74-82
Tier III:				1981*
Terrestrial wildlife testing....				
Aquatic animal testing..........				
Plant studies...................				
Nontarget insect testing........				
NONTARGET ORGANISMS AND ENVIRONMENTAL EXPRESSION:				
Microbial agents				
Tier I:				
Avian oral......................				
Avian injection test............				
Wild mammal testing.............				
Freshwater fish testing.........				
Freshwater aquatic invertebrate testing.				
Estuarine and marine animal testing.				
Plant studies:				
Nontarget insect testing......				
Honey bee testing............				V

*Prior to 1981, biorational pesticides (microbials, biochemicals), were subject to the same data requirements as conventional pesticides on a case-by-case basis.

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED			
BIORATIONAL PESTICIDES (Continued)	1947-62	63-70	71-73	74-82
Tier II:				
Terrestrial environmental testing.				1981*
Freshwater environmental expression tests.				
Marine or estuarine environmental expression tests.				
Tier III:				
Terrestrial wildlife & aquatic organism testing.				
Avian pathogenicity/Reproduction test.				
Definitive aquatic animal tests.				
Aquatic embryo larvae and life cycle studies.				
Aquatic ecosystem test..........				
Special aquatic test (reserved).				
Plant studies..................				↓

*Prior to 1981, biorational pesticides (microbials, biochemicals), were subject to the same data requirements as conventional pesticides on a case-by-case basis.

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED (Continued)

DATA REQUIREMENT	DATE ESTABLISHED			
BIORATIONAL PESTICIDES (Continued)	1947-62	63-70	71-73	74-82
Tier IV:				1981*
Simulated and actual field tests (birds, mammals).				
Simulated and actual field tests (aquatic organisms).				
Simulated and actual field tests (insect predators, parasites) (reserved).				
Simulated and actual field tests (insect pollinators) (reserved).				

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*Prior to 1981, biorational pesticides (microbials, biochemicals), were subject to the same data requirements as conventional pesticides on a case-by-case basis.

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED (Continued)

DATA REQUIREMENTS	DATE ESTABLISHED				
PRODUCT PERFORMANCE	1910-46	47-58	59-78	79-81[c]	82[d]
EFFICACY OF ANTIMICROBIAL CONTROL AGENTS					
1. Public Health Uses[a]		X	X		
2. Non-Public Health Use[b]		X	X	X	X
EFFICACY OF AQUATIC PEST CONTROL AGENTS					
1. Aquatic herbicides		X	X		
2. Swimming pool algicides		X	X		
3. Industrial cooling water microbiocides		X	X		
4. Pulp and papermill water system microbiocides		X	X		
5. Antifouling biocides		X	X		

[a] Antimicrobial products intended to control microorganisms infectious for man in any area of the inanimate environment where these microorganisms may present a hazard to human health. These include sterilizers, disinfectants, carpet sanitizers, laundry additives, and virucides.

[b] Antimicrobial products not directly related to public health such as control of odor-producing bacteria, bacteria causing spoilage, deterioration, or fouling of materials such as paint or industrial fluids, and microorganisms infectious only for animals.

[c] Initial efficacy data waiver (44 FR 27933, 40 CFR, Part 162; May 11, 1979).

[d] Expansion of efficacy data waiver (47 FR 40659, 40 CFR, Part 162; September 15, 1982).

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED (Continued)

DATA REQUIREMENTS	DATE ESTABLISHED				
PRODUCT PERFORMANCE	1910-46	47-58	59-78	79-81c/	82d/
EFFICACY OF FUNGICIDES AND NEMATICIDES					
1. Fungicides	X	X	X		
2. Nematicides			X		
3. Control of organisms producing mycotoxins				X (Reserved)	X (Reserved)
4. Wood and wood products treatments		X	X		
5. Mold and mildew on surfaces		X	X		
EFFICACY OF TERRESTRIAL PLANT CONTROL AGENTS					
1. Terrestrial herbicides		X	X		
2. Plant regulators			X		
3. Desiccants			X		
4. Defoliants			X		

c/ Initial efficacy data waiver (44 FR 27933, 40 CFR, Part 162; May 11, 1979).

d/ Expansion of efficacy data waiver (47 FR 40659, 40 CFR, Part 162; September 15, 1982).

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED (Continued)

DATA REQUIREMENTS	DATE ESTABLISHED				
PRODUCT PERFORMANCE	1910-46	47-58	59-78	79-81c/	82d/
EFFICACY OF INVERTEBRATE CONTROL AGENTS					
1. Foliar and soil treatments	X	X	X		
2. Outdoor ornamental lawn treatments		X	X		
3. Livestock, poultry, fur and wool bearing animal treatment		X	X	X	
4. Control of pests of humans and pets		X	X	X	
5. Structural termite control		X	X	X	
6. Premises treatments-cockroach		X	X	X	
7. Fabric treatments		X	X	X	
8. Mosquito control		X	X	X	
EFFICACY OF VERTEBRATE CONTROL AGENTS					
1. Fish control agents					
2. Terrestrial amphibians and reptilians		X	X		
3. Avian toxicants, repellents		X	X		

c/ Initial efficacy data waiver (44 FR 27933, 40 CFR, Part 162; May 11, 1979).

d/ Expansion of efficacy data waiver (47 FR 40659, 40 CFR, Part 162; September 15, 1982).

SUMMARY OF DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES AND DATE ESTABLISHED (Continued)

DATA REQUIREMENTS	DATE ESTABLISHED				
PRODUCT PERFORMANCE	1910-46	47-58	59-78	79-81c/	82d/
EFFICACY OF VERTEBRATE CONTROL AGENTS (Continued)					
4. Mole toxicants		X	X		
5. Bat toxicants		X	X	X	
6. Commensal rodenticides		X	X	X	
7. Rodent repellents		X	X		
8. Mamalian predacides		X	X	X	
9. Domestic Dog and Cat Repellents		X	X		
10. Browsing Animal Repellents		X	X		

c/ Initial efficacy data waiver (44 FR 27933, 40 CFR, Part 162; May 11, 1979).

d/ Expansion of efficacy data waiver (47 FR 40659, 40 CFR, Part 162; September 15, 1982).

STATEMENT OF MAUREEN K. HINKLE, POLICY ANALYST

NATIONAL AUDUBON SOCIETY

Mr. Chairman and members of this subcommittee, the National Audubon Society appreciates this opportunity to testify on the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) which needs to be reauthorized for FY 1984 program.

We have been requested to limit testimony today to the differences between the House and Senate reauthorization bills. Because the differences between the House and Senate bills go to the heart of the likelihood of addressing fundamental problems involved in regulation of pesticides, our discussion of the House and Senate bills must include the reasons the House bill is needed, as opposed to the Senate bill. In addition, the most serious problem of public confidence in EPA to regulate has been highlighted by recent disclosures of fraudulent testing conducted on a high percentage of pesticides now registered by EPA. Moreover, ongoing congressional investigations finding White House interference in regulation, and in general politicizing the regulatory process have prompted a great deal of press attention. As a result, public trust will not be restored by congressional inattention to problems that are now a matter of everyday headlines.

On May 17, 1983 the Chairman of the House Agriculture Committee released a statement on H.R. 2785 which explained,

> "We have moved this bill quickly through the Agriculture Committee and now the House because it is very important that we authorize adequate funding for pesticide programs and assure continuity for the scientific advisory panel. But I hope everyone who is concerned with this important issue will note that the bill extends the basic FIFRA authority for only one year. This was done because the Agriculture Committee has committed itself to a thorough study of a wide range of important proposed changes in the basic law, and we want to try to get decisions on those changes before any further FIFRA extensions."

Audubon supports the House reauthorization of FIFRA for $64.2 million, $8 million above the President's budget for FIFRA activities. We agree with the House subcommittee chairman's statement that "This bill is a necessary step, taken in a spirit of compromise, to provide a sound basis for continuing EPA pesticide programs and to provide a step toward our further study of changes in those programs." The ranking minority member urged bipartisan support for the House bill and the additional funding.

Audubon's testimony before the House subcommittee on April 6, 1983 discussed at length the resource implications of the budget cuts already incurred in the pesticide programs. A memo obtained from Congressman Mike Synar, (Chairman, House Subcommittee on Environment, Energy, and Natural Resources of the Committee on Government Operations), emphasizes the brutal implications of previous budget cuts and of any cut that is made at this point in time.

In a confidential memo from the Director of the Office of Pesticide Programs, Ed Johnson, to former Assistant Administrator, John Todhunter, entitled "Impact of FY-82 Turbulence," there are references to "lingering bitterness and other effects of previous outplacement efforts in 1981." Mr. Johnson's view of the budget cuts in its institutional and historical context stated in no uncertain terms, "We have repeatedly had our plans reduced to shambles by multiple rounds of reductions. When significant changes of this sort occurred for both the 82 and 83 budgets, we have tried to reflect them realistically through reduced program outputs. . . It now seems clear that these output projections may be too optimistic . . . [which] has implications for program plans, performance standards, and employee morale. . .

. . . the bottom line[s] . . . is]to] . . . respond to the reality of our situation by adjusting our extremely ambitious commitments (at least qualitatively). The public programmatic forecasts we are now making in budgetary and other documents are unrealistically upbeat. For example, in pursuit of our goal of eliminating all backlogs, we plan to improve our working relationship with industry and to diminish both industry burden and EPA workload through partial or complete de-regulation of some categories of pesticide products."

Mr. Chairman and members of this subcommittee, this memorandum was written a year ago. The backlogs referred to have been eliminated. The official who ordered negotiations with industry to reduce agency workload has been dismissed. However, the procedures, the process, the reorganization incorporating his goals have been put in place over the past year.

The new administrator can, of course, alter these changes, but they are as Mr. Johnson's memo of March 15, 1982 states, "many and pervasive."

The National Audubon Society submits that without a one year reauthorization, together with the increased funding passed in the House, the flexibility of Administrator Ruckelshaus to change these far-reaching policies, restoring a measure of public trust, and beginning a measure of meaningful regulation will not be available to him.

Our reservation with the House Report and the House reauthorization bill, H.R. 2785, is too much reliance on the Science Advisory Panel (SAP) to calm the troubled waters at EPA. Audubon shares the confidence in the SAP to help EPA, and new Administrator Ruckelshaus. In view of the chaos and political pressures that have rent the agency over the past two years, there is no substitute for congressional oversight and legislative correction.

The SAP did indeed operate for seven years as an open, accessible scientific forum. Review of regulatory decisions was openly discussed, with opportunity for participation by the public. Affected industry parties routinely participated with written and oral presentations. I attended over 60 percent of the panel meetings over the seven years. The panel members openly debated differences, contradictions, and problems. Panel members referred particularly contentious issues.

The SAP however is not a substitute for quality science within EPA. As esteemed, respected, knowledgeable, extremely competent and articulate as the panel members are, they are very busy persons who could devote only part time to FIFRA. In addition, they had to rely on the information EPA gave to them within the time frame imposed by EPA. The problems and issues were not always framed for them in ways they could address efficiently or thoroughly. Problems were presented on a case-by-case basis. Panel members were not supposed to get into larger issues. When the need for a particular chemical ultimately rested on the unhappy fact that there were no alternatives, the panel would ask "why are we in this dilemma?" They could have asked why they were put through the whole exercise if the outcome was preordained by the one reality: it is the only chemical available.

The seven panel members who served in an exemplary way from 1976 to 1981 were summarily dismissed by former Administrator Gorsuch (Burford) on the grounds that their terms had legislatively expires. Technically they had. Yet Mrs. Gorsuch ordered a new panel to be formed, an action delayed because of the alternate means pursued to enable and bring about the new panel.

In the interim, EPA needed the functional equivalent of a scientific review of several issues. The former panel members were accordingly resurrected as consultants to review the toxaphene cancellations on a confidential basis, and to review the registration guidelines in a public meeting.

Science can be better served, in our view, if the former panel members can continue to serve EPA as consultants, together with the current SAP when the issue involves expertise former members can provide, or when absences reduce the operating efficiency of a meeting. In addition, Roy Albert, who served as Chairman of EPA's Cancer Assessment Group in the 1970's and possesses invaluable insights into the history and significance of risk assessments of problem pesticides, could be requested to participate as a consultant to the new panel. His perspective regarding the consequences of overregulation and underregulation would help the panel to keep the larger issues in mind as they address the details of the individual cases and issues presented to them.

The 1972 FIFRA was intended to regulate pesticides in a comprehensive scheme of pre-market tests, enforcement of the label as a legal document, restricted use by certified applicators to prevent accidents and misuse, and monitoring to ensure that the predicted behavior of pesticides were not behaving in ways that caused problems. Unreasonable adverse effects were to trigger intensive review and cancellation if necessary to protect the public.

Implementation of such an ambitious scheme was at best difficult.

Funding for the program was reduced each year. The handful of cancellation cases successfully removing the widely-used and ubiquitous chlorinted hydrocarbons lulled the public into a false assumption that regulation was proceeding apace. What happened in the 1970's was preparation for the deregulatary efforts of 1981-82.

First, EPA found cancellation cases too resource intensive, and determined in 1979 to allow cancellation proceedings only when registrants appealed EPA decisions on the ground such decisions went too far. If the public disagreed with EPA decisions as not far (strong) enough, hearings could take place only after a district court hearing.

Without the force or counter pressure of participation from external parties, the comprehensive scheme, aimed at preventing unreasonable adverse effects on man and the environment, began to unravel.

Secondly, the better the data, the stronger the case could be made against the chemical, e.g., Aldrin/Dieldrin. Bad or incomplete data could not be used against a chemical. In 1976 EPA had to have called to its attention the fact that its registration files were "useless to the point of scandal." (NAS-NRC Report on EPA, V. 11a - "Decision Making in the Environmental Protection Agency, @244.) A complete data base did not exist for any chemical, let alone most. As the world now knows, an astoundingly high number of studies - 737 - submitted to EPA in support of pesticide registration has been found to be invalid as a result of fraudulent tests done by IBT Laboratories. Not only is a large proportion of pesticides now on the market registered on the basis of IBT tests, most continued to be registered with little or no data at all.

The two factors are related. As RPAR's were graduated after years of intensive review, EPA determined to cancel only minor or out of date uses, uses that would not be appealed or contested by registrants. RPAR itself, however, had been anathema to industry, and became a target for reform. For its part, the agency believed that mass review of pesticides on the basis of chronic (long-term) effects simply caught too many chemicals to evaluate and review adequately. To take action on those chemicals triggering chronic toxicity criteria meant regulatory action so broad as to remove from the marketplace or cast doubt on the safety of most chemicals. Thus the agency was ripe for reform for RPAR proposed by industry. In response to industry requests, RPAR was removed as a high visibility entity, and dropped into the Registration Standards System. Moreover, since nearly all regulatory decisions could be delayed indefinitly largely because of data gaps, risk chemicals no longer need to be of concern to either EPA or to the registrants. In the Registration Standards System, registrants negotiate what tests will be undertaken and review is delayed until the study taking the longest to generate is submitted. At some far distant future time evaluation and action, if needed, will take place. The rationale of the agency is: action prior to "definite proof" would be premature or unfeasible. The capstone of all this regulatory reform is EPA's justification that the intensive review (RPAR) costs, on an average, around $1 million per chemical (two-three year investigation). If the regulatory result is a minor restriction such as gloves and a respirator, or rubber boots, the result is what NEW FARM MAGAZINE calls "EPA's Million Dollar Boots." (February 1983. pp. 12-14.) In other words, if the registrant spends millions of dollars on tests, and EPA spends millions on intensive review, and the only result is a minor restriction, the registration standards process can accomplish the minor (or risk-reducing) restriction without the great expenditure of public and private funds.

This rationale rests on the importance of efficiency and keeping products on the market. This policy assumes the public does not need to be involved, and has no role in such regulatory decisions.

The assumption that the public does not need to be involved in regulatory decision is the basis for the Monsanto case reported on April 12, 1983 in the U.S. District Court for the Eastern District of Missouri. The judge in that court ruled that public disclosure of submitted data "is to permit the public to share in the regulation of the pesticide industry." (Monsanto Company v. Acting Administrator United States Environmental Protection Agency, No. 79-366 C(1) Memorandum Opinion dated April 19, 1983, at 41)

EPA is accordingly not releasing any information to any person, pending appeal to the Supreme Court. This means that almost no information has ever been released to the public.

Prior to 1972, the USDA's Pesticide Regulation Division (PRD) refused to give outside scientists and other members of the public access to safety data on pesticides. USDA regarded all data as trade secrets.

After PRD was transferred to EPA, Administrator Ruckelshaus reevaluated PRD's trade secret policy and decided it was incorrect. In January, 1972 EPA agreed that safety data should be released to the public. The 1972 FIFRA thus required the Administrator to make available to the public, within 30 days after registration, the data called for in the registration statement. The exception was trade secret data protected under Section 10. Thereupon, companies routinely designated all information except labelling as "confidential," and no data was made available to the public.

To correct this situation, and to make health, safety and environmental data routinely available to the public, both Houses of Congress agreed to the 1978 amendments. Senators Lugar and Leahy were singularly responsible for passage of the Section 10 language in 1978. As you know, as soon as the 1978 amendments passed, chemical companies added trade secret disclosure to ongoing data compensation litigation. These ten court suits effectively prohibited disclosure of information and implementation of Section 10 until resolution of the litigation. The first of these suits was concluded on June 12, 1981 when the Southern District of New York vacated the order, lifting the injunction against release of trade secrets on 12 companies (bringing the first case). As a result of this case, and subsequent ones ruling that data was releasible, companies descended on Congress in 1981 and 1982 to change Section 10.

Except for the AFL/CIO case allowing some data to be reviewed, and for release to Audubon and the Environmental Defense Fund in several instances over the years, no data has been released. The Monsanto case, finding several portions of Sections 3 and 10 to be unconstitutional has once again paralyzed the registration and data disclosure processes at EPA. The Monsanto case is the latest in a series of industry lawsuits aimed at either circumventing or directly challenging the carefully considered and balanced amendments to FIFRA in 1972, 1975, and 1978.

The problems with FIFRA, and the ambivalent record of the EPA in administering the pesticide program will persist until the Congress amends FIFRA to provide the agency not just with adequate, unambiguous authority, but also the political and administrative independence needed to take and defend decisive actions to protect the public health and environment.

Recent disclosures in the press regarding the Industrial Bio Test Laboratories, Inc. (IBT) are shocking the public regarding the safety of pesticides now on the market. The IBT case deserves official attention by the Congress. It is an old case, dating back to an April 12, 1976 audit of one of IBT's laboratories. By June 10, 1977, EPA had placed a moratorium in granting new registrations or tolerances based on toxicological data developed by IBT. In the next year, a flurry of IBT related activities occurred including additional laboratory audits documenting that the problems discovered earlier were more widespread than previously thought, a series of meetings of EPA and FDA officials to determine appropriate regulatory actions in the wake of the IBT audit findings, and referral of the IBT case to the Justice Department for consideration of a possible Grand Jury investigation. The events over the last seven years on IBT and EPA's schizophrenic handling of the case would consume too many pages. Instead, attached for the record are a series of documents including several extremely informative ones from other countries and international organizations, on the history of this case.

These documents need to be carefully reviewed and considered for their policy implications. Congressional oversight is desperately needed in order to get some answers on the IBT case. Several serious questions arise out of an examination of the IBT validation process. Why did EPA adopt a policy allowing the chemical company sponsors IBT tests to selectively validate IBT studies? Why has the agency waited until the trial in Chicago to make public some of the numbers on IBT studies? Why has EPA taken no regulatory action against pesticides with known, major IBT data gaps? Some pesticide registrations, according to an EPA FY 1979 request for supplemental appropriations: "The total cost of this (IBT validation and replacement study review) program would be 185-450 person years and includes some 4,300 test results . . ." Why should public funds be spent for wrongdoing of a few companies?

Mr. Chairman and members of this subcommittee, the IBT case points out several weaknesses of the current FIFRA statute. The EPA lacks clear authority, and a mandate, to hold, suspend or cancel pesticide registrations when it is discovered that fraudulent data was submitted to the agency, and involved in granting the registration action. Without a directive from Congress, the FIFRA statute now encourages and condones sloppy data. EPA's handling of IBT data rewards irresponsible companies, and penalizes those responsible companies which immediately acted to conduct and submit to EPA studies replacing those done by IBT.

The integrity of the pesticide regulatory program is at stake. I share your hope that Administrator Ruckelshaus will move decisively to correct the many problems he is faced with in this troubled program. He will need help and support from the Congress because many long-overdo agency actions will be controversial and unpopular. Audubon urges this committee to play an active and constructive role in the process of first improving the agency's ability and resolve to administer FIFRA as intended by Congress, and second, to enact the many critically needed amendments to the statute so that EPA can, and will do its job with a sense of purpose and in the public's interest.

Mr. Chairman and members of this subcommittee, Audubon therefore urges you to vote out a one-year reauthorization bill and authorize the $64.2 million contained in H.R. 2785, as a good faith effort to begin the process of restoring public confidence in industry, in EPA, and in Congress.

STATEMENT OF JAY FELDMAN
NATIONAL COORDINATOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

Thank you for the opportunity to speak with you today. I am Jay Feldman, National Coordinator of the National Coalition Against the Misuse of Pesticides (NCAMP). I am pleased to be here to address S. 1263 and the extension of our nation's pesticide control law --the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Our coalition's interest in FIFRA grows out of the experiences of our broad-based network of organizations and individuals in 50 states across the country. NCAMP is composed of members with common concerns about pesticide hazards and safety, including family farmers, farmworkers, beekeepers, chemical workers, and urban and rural residents.

The coalition seeks protection for all who may be exposed to pesticides, either through their employment, as consumers, as victims of contaminated drinking water, or as neighbors of dump sites, sprayed fields, forests or right-of-ways. NCAMP also promotes alternatives to excessive pesticide use and misuse, such as Integrated Pest Management (IPM), in an effort to reduce damage to humans and the environment, ease economic burdens over the long-run and improve general public and occupational health.

Reject S. 1263's Two-Year Extension of FIFRA

We have come here today to urge you to reject S. 1263, unless it can be amended to provide for only one year of program funding.

We take this position for one major reason: The American people cannot wait two years for its legislators to take a look at the serious deficiencies in federal protections from toxic pesticide contamination and poisoning. Neither can those people throughout the world who use American-made pesticide products wait two years.

Accept H.R. 2785 as Adopted by the House

In place of S. 1263's two-year reauthorization, we ask, Mr. Chairman, that you substitute language which would simply keep our nation's pesticide regulatory program going for a one-year period while Congress conducts a broad review of the program and takes up legislative proposals.

As you know, the U.S. House of Representatives just last week took this approach when it passed H.R. 2785 on a voice vote to extend FIFRA unchanged for one year.

We endorsed the House bill because of the House leaders' commitment to take up legislative proposals which seek to improve FIFRA and better protect the public.

Why Put the American People on Hold for Two Years?

When the debate on FIFRA reauthorization began months ago, we, at that time, urged expeditious review of problems related to pesticide contamination and poisoning. We proposed that Congress put FIFRA review and legislative proposals to improve the statute on a fast track and give the American people the hearing they deserve.

A two-year extension of this statute puts the American people and their safety on hold. Unfortunately, Congress cannot hold back contamination and life-threatening effects during that two-year period and we do not always have the technology to clean-up or repair after the contamination has occurred or a life has been destroyed.

Communities that no longer have safe drinking water because their ground water is contaminated with pesticides do not accept the slow-track approach being proposed in S. 1263. Neither do people in towns where herbicides, once used in Vietnam, drift. Neither do people consuming beef or fish that show suprisingly high levels of dioxin, perhaps the most deadly chemical contaminant known to the human race. Neither do millions of homeowners across this land who, given the construction of their homes, may have inadvertently poisoned their families when treating for termites. Neither do farmers and farmworkers of our country who go to bed sick and suffer chronic health problems associated with pesticides. Neither do unborn and newborn children whose exposure to contaminants jeopardizes their future health.

Mr. Chairman, the numbers of people, the numbers of communities and the number of problems add up. The problems are not new. There are just more of them since we presented them to you last year. Since last year, there is yet additional documentation which indicates that these problems reflect a regulatory control program that is not working.

In our view, the Senate must set a course which looks at FIFRA and its problems in an expeditious manner. S. 1263 does not do this. Voting this bill out of the Senate Agriculture Committee is like telling the American public that there are more important things to do than worry about the contamination of their communities and the poisoning of their families.

Some on Capitol Hill have told us that running for reelection is more important than seeking solutions to problems that may be controversial in nature. We do not want to believe that this is the general view.

If it is our view that the American public wants to see Congress strengthen FIFRA's public and environmental protections against the hazards of pesticides, who then wants to put the American people on hold for two years? All indications point to the chemical industry. In testimony before the U.S. House of Representatives, the National Agricultural Chemicals Association (NACA) has said, "The new EPA Administrator should be given an opportunity to familiarize himself with the pesticide program before substantive changes to FIFRA are given further consideration by Congress."

Interestingly enough, the EPA scandal has resulted in official comments which belie this argument. Mr. William Ruckelshaus, the new EPA Administrator, has been quite clear in his public statements that because he believes in the professionalism and expertise of the EPA staff, he does not see getting the agency back on track as a long-term proposition. On the one hand, neither Mr. Ruckelshaus nor any Administration official wants to paint a picture of an EPA so out of control that it will take years to rebuild. On the other hand, the Administration, supported by industry, wants to forestall action for two years on the premise that time is needed to rebuild.

As you know, Mr. Chairman, no reauthorization of FIFRA and a simple one-year reauthorization is one and the same to those who happen to be the unfortunate victims of a law that is not working to protect them. Without a reauthorization bill, EPA's pesticide program will not shut down. It will continue to operate on a Continuing Resolution or an EPA Appropriations Bill as it is, in fact, operating today and has been since fiscal year 1982.

When we get down to the real issues of public and environmental protection and in view of the magnitude of the pesticide problems making their way to the front pages of newspapers across our country, H.R. 2785 does nothing that a Continuing Resolution or an EPA Appropriations Bill could not achieve. The existence of a permanent Scientific Advisory Panel (contained in both House and Senate bills) is not worth the price of Congressional inaction, since SAP members can continue to be retained as consultants.

Yet, we support the House bill because it is backed by a very serious and important commitment in the House leadership to take up legislative proposals.

Legislative Remedies for the Pesticide Problem

Representative Tom Harkin, Member of Congress from Iowa, is planning to introduce legislation, entitled the National Pesticide Hazard Prevention Act, to improve the public health and environmental protections from pesticide hazards. A coalition of members is forming in the Senate around the same issues. Senators from states which are seriously and adversely affected by pesticides in their groundwater, like Senator William Proxmire, are leading a FIFRA reform effort. Other aspects of the pesticide problem cause other members of the House and Senate to seek reform.

The National Pesticide Hazard Prevention Bill would establish a more protective pesticide registration program at EPA by closing numerous loopholes in the current law which allow safety standards to be circumvented.

In addition, the bill will assure:

- Improved protection for humans exposed to pesticides, with particular emphasis given to those handling chemicals, those working on the farm,and children;
- adequate enforcement of federal law and legal remedies for those who have been damaged by pesticides;
- public participation in pesticide decision-making at EPA so that all the facts can be brought to bear before a registration decision is made as well as after an application is granted, and;
- products are tested for effectiveness to ensure that chemicals perform as the manufacturers claim.

The bill has our backing, as well as a broad coalition of national consumer, health, labor and environmental groups.

The Pesticide Problem In Review

The need to adjust FIFRA grows out of the long list of disturbing events which we attribute to pesticide use and misuse. IGNORING THESE SIGNALS NOW WILL ONLY COST OUR NATION MORE LATER.

We have seen crop damage, fish, bird and bee kills, contaminated drinking water, poisoned food, contaminated homes and sickness. At the same time, product effectiveness appears to be waning and insect and seed resistance to these chemicals are on the rise. Insect resistance is reported in nearly 400 species and farmers are reporting weed resistance to herbicides.[1]

Just as EPA shut down its Pesticide Incident Monitoring System (PIMS), which tracked rates of poisonings and other pesticide-related problems, the only state with a reporting system of its own, California, saw a 27 percent increase in poisoning in 1982 and a 78 percent increase in the number of days poison victims required hospital care.

Important information has recently been brought to light by a Staff Report on the EPA Pesticide Regulatory Program, produced by the House Agriculture Subcommittee on Department Operations, Research and Foreign Agriculture. One of the most serious findings of the report is the extent of the missing health and safety data for pesticide products registered by the EPA.

That is, beyond the extensive problem of products having been registered with faulty data generated by companies like Industrial Bio-Test Laboratories, Inc., data simply does not exist for most products' ability to cause cancer, genetic damage and birth defects. Using data from EPA's files, the Staff Report reveals discomforting figures indicating:

- between 79 and 84 percent of the products on the market have not been adequately tested for their capacity to cause cancer;
- between 90 and 93 percent of the same products have not been adequately tested for their ability to cause genetic damage;
- between 60 and 70 percent have not been fully tested for their ability to cause birth defects, and;
- between 30 and 46 percent have not been fully tested for reproductive effects.[2]

This Committee has been aware of this problem, to some extent, since 1980 when the U.S. General Accounting Office published its report, Delays and Unresolved Issues Plague New Pesticide Protection Programs. The report states,

> [A]ccording to EPA officials, key tests required under current EPA regulations have not been performed for many of the 514 registration standards pesticides. Included are

> long-term (up to 3 years) animal feeding studies which show whether a pesticide causes chronic effects, such as cancer or birth defects, in animals. An official told us that EPA needs the results of these tests to make even preliminary decisions concerning a pesticide's safety and whether it should be reregistered.[3]
>
> Our 1975 report to Congress stated that the public is exposed daily to many pesticides which are not supported by animal and environmental safety studies. The situation has not improved. During our current review, an EPA official told us that the basis for many tolerances granted by the Food and Drug Administration is still obscure. According to the official, little, if any, documentation exists explaining how or why these tolerances were granted. Additionally, the Assistant Administrator for Pesticides and Toxic Substances stated that not much difference exists between the present condition of EPA's test data files and those that existed at the time of our 1975 report.[4]

How does EPA gain public confidence in its work and the registrations it gives to pesticide products, if the data underlying its determinations are faulty or absent?

Also, unbeknownst to the community, a pesticide may be in use under one of a number of increasing "special local need" or "emergency exemption" permits. In the four year period between 1978 and 1982, the issuance of emergency exemptions under the "specific," "crisis," and "other" categories rose from 149 in FY 1978 to 673 in FY 1982; a 352 percent increase. From FY 1976 to FY 1978, the number of "special local need" registrations issued jumped 1,216, from 440 to 1656.

The concern about the rising numbers grows out of the Staff Report's and our own information about these types of registrations.

According to the Staff Report,

> Pesticide registrations granted through Section 18 ["emergency exemption"] and 24(c) ["special local need"] almost always entail significantly less complete and rigorous data requirements and scientific reviews.
>
> Possibly serious adverse effects on the environment and wildlife may occur as a result of uses registered under Section 18 and 24(c) during the sometimes extended period during EPA analyzes the potential impacts associated with pending Section 3 applications for similar uses.[5]

Product Efficacy Information is Essential

Beyond the lack of data supporting a pesticide product's registration, the pesticide user and the public has no real assurance that the product will perform as the manufacturers' claim.

EPA explains efficacy requirements under FIFRA in the Federal Register of November 24, 1982 where the Agency proposes to further reduce the efficacy data required.

> Those products for which an efficacy data requirement was continued in 1979 were products which, if they lacked efficacy, could potentially have significant public health effects, such as mosquito control products, rodenticides, certain other invertebrate and vertebrate control agents, and antimicrobial products. The Agency now believes that because many of the "public health" use patterns identified at the time are more of an aesthetic and nuisance problem than one of public health and are in any case adequately covered by other regulatory mechanisms offering assurance that the products are efficacious, and because the efficacy of products for other of these uses are adequately discernible by the user, marketing of inefficacious products is unlikely.
>
> The Agency is proposing to extend its current waiver to efficacy data for all uses of pesticides except those where control cannot reasonably be observed or determined by the user and lack of control is a clear adverse health effect. (Emphasis added)[6]

EPA, under FIFRA has waived most efficacy data believing that users are protected since "pesticide producers are aware that they are potentially subject to damage suits by the user community if their products prove ineffective in actual use." However, this kind of statement does not provide much consolation to farmers like those in Kennewick, Washington, who, after investing in herbicides they allege to be inefficacious, are now seeking legal action against some chemical manufacturers.

In addition to the potential economic harm suffered by the farmers, Dr. Stephen Frantz, a public health official with the New York State Department of Health, says that the consequences of using an inefficacious product can be great and, "I want to stress that the negative consequences are of public health significance, but the effects are generally of a chronic nature rather than acute." Dr. Frantz continues,

> There have been problems with efficacy for rodenticides as well as other products as evidences by EPA's own testing laboratory at Beltsville (D. Peacock and S. Palmateer, 1979, "Comparison of EPA Animal Biology Laboratory and Company Laboratory Efficacy Data for Federally Registered Rat and Mouse Baits"). Most products passed by companies failed when tested by EPA for registration purposes.[7]

Seeking a Preventive Approach

The same inclination that supports a two-year reauthorization of FIFRA may promote the notion that we have time and action is not necessary now. Rather than face crisis after crisis, we seek a preventive approach to the pesticide problem. We would like to minimize health and environmental damage and therefore are calling for a more rigorous program of pesticide registration.

Our national pesticide policy, or lack thereof, is helping us to dig ourselves into a social and moral dilemma so deep that we may not be able to climb out. The recent EPA action on Toxaphene is a case in point which raises the ultimate question of whether we can really clean up after our mistakes.

In May of 1977, EPA issued a "Notice of Rebuttable Presumption Against Registration and Continued Registration of Pesticide Products Containing Toxaphene." In November, 1982, over five years later, EPA finds without equivocation that

> [T]oxaphene induces cancer in laboratory animals and is acutely and chronically toxic to aquatic life and birds (including endangered species). Examination of the patterns of use and the potential for exposure indicates that toxaphene is extremely persistent, moves readily through the environment, and contaminates habitats of vulnerable aquatic and avian species at levels sufficient to reduce their populations, and that humans are exposed to toxaphene through occupational contact and contamination of a range of food products, particularly fish. The potential risks to wildlife and human health resulting from toxaphene exposure were found to be extremely high.[8]

The public is then told by EPA that this chemical's use for scabies treatment of beef cattle and sheep are retained, as are several minor uses, including application to bananas and pineapples in Puerto Rico and the Virgin Islands. Reading the EPA notice further reveals that a more complicated regulatory scheme is established to allow the continued use of existing toxaphene stocks until 1986. The same chemical EPA has found to accumulate in our food chain has received the following limitation on further use.

> Existing stocks of toxaphene may be used for specified periods of time under very limited terms and conditions partly because such use is judged to be the most desirable means of achieving disposal of those stocks.[9]

The point here is that EPA really has no satisfactory solution to a problem it has finally identified. The Agency has merely identified a "most desirable" solution. EPA's own staff has said that there is so much existing stock (several million pounds) that toxic waste dumps would be unable to adequately dispose of the volume safely. The Agency conclusion: It would be better to disperse the pesticide at low doses in the environment.

So the dilemma surrounding the registration of a pesticide persists. The manufacturer exhausts its supplies while the public health and environmental risks continue.

Conclusion

Mr. Chairman, we appear here today on behalf of the thousands of individuals who have fallen victim to a system of pesticide control that is not working. These are people who face exposure problems that are frustrating. They seek answers and find none. They call government agencies for assistance and tell us that they find little satisfaction.

These are the same people that have been told that most of what we have learned about chemicals like toxaphene was not known when the chemicals were first introduced. We have been told this about dioxin, although early 1965 industry memos have since refuted unequivocal claims of safety.

Mr. Chairman, this Committee has an opportunity to set a more cautious tone, to take precautions and to seek answers before problems occur. This Committee can choose this responsible course, or choose to tell another generation that we just did not know.

RESOURCES

[1] Dale Bottrell, Integrated Pest Management, Council on Environmental Quality, December, 1979, p.9.

[2] Staff Report, EPA Pesticide Regulatory Program Study, Subcommittee on Department Operations, Research and Foreign Agriculture, Committee on Agriculture, U.S. House of Representatives, 97th Cong., 2nd Session, December 17, 1982, p. 187.

[3] U.S. General Accounting Office, Delays and Unresolved Issues Plague New Pesticide Protection Programs, CED-80-32, February 15, 1980, p. 15.

[4] Ibid., p. 19

[5] Staff Report, p. 114.

[6] 47 FR 53196, Pesticide Registration; Proposed Data Requirements, Nov. 24, 1982.

[7] Dr. Stephen Frantz, letter to EPA dated May 11, 1983 re. 40 CFR 158, Pesticide Registration; Proposed Data Requirements, pp. 1-2.

[8] 47 FR 53785, Intent to Cancel or Restrict Registrations of Pesticide Products Containing Toxaphene, Nov. 29, 1982.

[9] Ibid.

STATEMENT OF JACQUELINE M. WARREN

NATURAL RESOURCES DEFENSE COUNCIL, INC.

In recent months, the nation's attention has centered on allegations of widespread abuse at the Environmental Protection Agency in administering statutory programs designed to protect the public from exposure to toxic chemicals. In the case of EPA's pesticide program, there has been a continuing failure to assure that public health will be protected against dangerous pesticides. The problems that plague the EPA's implementation of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) arose prior to the current administration. During the past two years they have been greatly exacerbated. It is time for remedial action by Congress.

For a variety of reasons, unlike the other major environmental protection laws that have passed during the past 14 years, FIFRA remains a stepchild. Despite a number of critical GAO and other congressional reports documenting serious problems in the EPA's pesticide program, neither the Senate nor the House authorizing committees ever thoroughly investigated the program between 1972 and 1982. Last year, however, the House Agriculture Committee's Subcommittee on Department Operations, Research and Foreign Agriculture issued an investigative report indicating serious and persistent problems in various aspects of EPA's pesticide registration program, especially in the procedures for evaluating the quality and generation of health and safety data by pesticide producers.

Given the rising public concern about pesticide safety sparked by the recent EPA furor, the IBT data falsification trial currently underway in Chicago, a host of recent incidents in many parts of the country involving pesticide contamination of drinking water and the food chain, pesticide contamination of homes due to improper termite control applications, and the detailed findings of the House Agriculture Subcommittee's December 1982 Staff Report documenting the magnitude of the threat to public health, we believe that the time is ripe for fundamental reform of this critically important statute. We are therefore proposing a draft legislative package of a series of explicit statutory amendments and bringing together a coalition of local, state and national groups to help assist its passage. The package will shortly be introduced in the House, which recently voted a one-year simple reauthorization of FIFRA. House leaders have pledged to hold hearings on proposed changes later in the year. We are seeking similar amendments in the Senate and will make the draft amendments available to this Subcommittee for your consideration today.

FIFRA has two goals: assuring the availability of an effective means of controlling pests, and doing so in a manner that assures public safety and prevents environmental degradation. So far it has failed on both counts.

With respect to effectively controlling pests, one need only reflect upon the fact that pesticide use has *increased* more than ten-fold in the past thirty years. Yet the percentage of food crops lost to pests has roughly doubled.[1]

In 1972, in response to a decade of public outcry, and to two major reports published in 1969, an investigation of USDA's pesticide program by Rep. Fountain, and an HEW report on the health effects of pesticides (known commonly as the "Mrak Report"), Congress enacted major amendments to FIFRA in the Federal Environmental Pesticide Control Act (FEPCA). The American public was told that FEPCA would amend FIFRA to assure human safety and protection of the environment.

The essence of pesticide regulation envisioned under the 1972 law can be stated simply. EPA would register (that is, license for sale) virtually all pesticides used in the United States. At this registration stage, the agency would make the critical regulatory judgement: could the pesticide be used without "unreasonable adverse effects" on man or the environment? If not, what restrictions should apply? If registered for use on a food crop, how much residue should be allowed on the food? EPA's judgement about these critical regulatory issues was to be based on experimental tests, submitted by pesticide companies. There were to be other program components, *e.g.*, licensing of applicators, enforcement, and packaging and disposal requirements, but the registration process was clearly the critical screening mechanism for federal action to protect humans and the environment.

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[1] Pimentel, *et al.*, "Benefits and Costs of Pesticide Use in U.S. Food Production, *Bioscience*, Vol. 28, No. 12, p.772 (Dec. 1978).

REREGISTRATION: A PROMISE UNFULFILLED

When FEPCA was enacted in 1972, Congress recognized that a crucial problem existed with the stock of previously registered pesticides. Throughout the decade of the 1970s, there was an explosion in scientific awareness of the potential dangers of pesticide use. For example, it was not until 1963 that cancer tests were required in the registration process; tests for birth defect hazards were not required until 1970; tests for the capacity of a pesticide to cause permanent genetic mutations were not required until 1972. However, thousands of pesticides had been registered before these new testing requirements were adopted. For that reason, there was an urgent need to review and upgrade existing pesticide registrations and to restrict or cancel uses that could not meet current safety standards.

To accomplish the task of reviewing existing pesticides, Congress required that by 1976, later extended to 1977, all previously registered pesticides would have to be reregistered. That is, all of the "old" pesticides would have to be scrutinized according to the scientific standards applied to new pesticides.

The history of EPA's attempts and ultimate failure to implement the Congressional mandate is well known to this Subcommittee. EPA initially planned only to require tests where none had been submitted because contemporary requirements were more demanding. The IBT scandal and other internal EPA investigations showed, however, that the Agency could not assume that existing studies were valid. The Agency then began a much larger task of reexamining the entire scientific basis for all previously registered pesticides. In the face of such an undertaking, EPA asked Congress for an indefinite extension of the reregistration deadline.

In 1978, Congress eliminated the explicit 5-year reregistration deadline. Instead, Congress told EPA to accomplish the reregistration of all pesticides "in the most expeditious manner practicable," and tinkered with the statute to facilitate achieving this result. In particular, the Agency was directed to give top priority to pesticides that result in post-harvest residues on food or feed crops.

Now, in 1983, EPA has still not achieved the statutory goal. Far from accomplishing reregistration "in the most expeditious manner practicable," EPA appears to have shifted resources out of the reregistration program and into registering new pesticides. Moreover, the full pesticides program staff has been reduced by 29%. Finally, it is not at all clear that EPA is giving top priority to pesticides that result in post-harvest residues on food and feed crops, or that are associated with risk of groundwater contamination.

We are not alone in voicing these concerns. In June 1981 and at subsequent hearings, the American Farm Bureau Federation has joined with environmental critics of EPA's pesticide program. In 1981 they said that "EPA has failed to review these product registrations under the more demanding standards of today's law ... and, according to EPA testimony a month ago, may take up to 40 years to complete the job. ...We believe EPA's record is a failure to protect farmers, ranchers, and other users, the public, and the environment."

Until recently, the real magnitude of the "data gap" (chemicals registered and in use with little or no adequate scientific studies) was not fully known. However, the December 1982 study by the House Subcommittee Staff, among its many other revealing findings, offers the first clue. Since EPA still cannot tell us today how many registered pesticides fully meet modern testing requirements, the House Subcommittee staff had to draw estimates of the data gap.

Consider, for example, the cancer test requirements. Presently, EPA requires two cancer bioassays for each basic active pesticide ingredient. Since there are approximately 600 basic active ingredients in substantial use today, there should be 1,200 cancer tests in EPA's files. EPA, however, has a total of only 456 tests on file. Since two cancer studies are required to support the registration of each pesticide, according to the House Subcommittee Staff Report, no more than 228 presently registered pesticides could meet current cancer test requirements. That means that at least 62% of all pesticides in use in the United States have not been adequately examined for their capacity to cause cancer - the second leading cause of death in the United States, resulting in 400,000 deaths a year, and striking more than one in four Americans.

In reality, the situation is even worse because there are more than two cancer tests on file for a number of pesticides. Thus, the total number of tests, 456, cannot simply be divided by the requirement of 2 tests per pesticide to determine the number of pesticides that meet current standards. The House Subcommittee Staff Report made adjustments for such multiple submissions and concluded that the probable number of basic active ingredients that meet today's cancer test requirements is actually between 96 and 127. In other words, in reality, an estimated 79% to 84% of all pesticides sold today in the United States have not been sufficiently examined for their capacity to cause cancer.

The statistics with respect to the tests required to assure that pesticides do not cause genetic mutations are even worse. There, the number of pesticides that do not meet today's test requirements lies somewhere between 90% and 93%.

As far as birth-defect causing properties are concerned, the matter is only a little better. There, the range of non-compliance is only between 60% to 70%.

We believe that Congress must move at once to correct these frightening shortcomings in the data base supporting pesticides to which the United States population is exposed in our food, our drinking water, our homes, and elsewhere. A specific, statutory timetable must be imposed on EPA to fill the data gap, and funds must be increased to enable the Agency to fulfill the mandate. The Agency should also be required to set reregistration priorities, starting with pesticides likely to be found in food and drinking water. Reregistration of all pesticides should be accomplished within seven years. A sunset provision should be added which would require suspension of any pesticide not reregistered within the established timetable, thereby assuring the active participation of registrants in the reregistration effort.

Concern over the data gap is not simply a concern about data to be gathered for no purpose. For every pesticide that Congress allows to be marketed without adequate health and safety data to support it, there should be a clearly marked warning, "The Government Does Not Know If This Pesticide Is Safe," for that is what the existence of a data gap means.

FIFRA OPERATES BY REACTION TO DISASTER, RATHER THAN PREVENTION

The failure of the reregistration and new registration programs to identify and prevent pesticide hazards has inevitably led to poisonings and environmental contamination. The public perceives pesticide regulation as a series of agency responses to pesticide disasters that are uncovered from time to time when the uncorrected errors of the past suddenly manifest themselves. For example:

(1) Suspension of the use of DBCP, nearly two decades after it was allowed on the market, came about only after employees manufacturing DBCP were discovered to be sterile, followed by the discovery of widespread DBCP contamination of drinking water supplies. Yet, nearly two decades ago, laboratory tests showed that DBCP caused testicular cancer. Why didn't the regulatory system work at the initial registration stage?

(2) TOK was similarly withdrawn from the market, after many years of use, when tests revealed it to have a very potent birth-defect-causing potential. Why didn't the system work at the initial registration stage?

(3) Groundwater contamination by Temik has been discovered in several states. When it was originally registered, the manufacturer contended that such contamination would not occur. Why didn't the regulatory system work at the initial registration stage?

(4) Hawaii's entire milk supply was contaminated by Heptachlor residues in cattle feed after EPA granted an exemption for its use. Why didn't the system work at the beginning?

(5) EDB, long in use as a fumigant, has now been shown to have an extremely high cancer-causing potential. Nevertheless, its use will be permitted for at least two more years. In the meantime, EDB-treated fruit is widely eaten and EDB contamination of groundwater is just being discovered. Why didn't the regulatory system work at the beginning?

(6) TORAK was withdrawn after hundreds of farm workers were poisoned. It proved to be an ineffective insecticide, although a very effective poison to humans. Why did it take human poisonings to detect its dangers?

(7) VACOR rat poison, long in use, was not removed from the market until after more than 150 children were irreversibly poisoned. Why was it necessary to sacrifice the health of these children for a proper regulatory decision to be made? Why didn't the regulatory system work at the beginning?

The 1972 amendments to FIFRA were supposed to move away from the trial and error method of detecting dangers to a systematic, preventive strategy for regulating pesticides. As the examples detailed above clearly show, the Act has failed in this task. The cloud of suspicion over pesticide safety cannot be removed until reregistration is completed, and the new registration system works effectively, that is, preventively.

Despite the obvious problems besetting the pesticide program at EPA, the current Administration has been committed to "reforming" the regulatory system, even though this means sweeping pesticides through the RPAR and reregistration process, and issuing new pesticide registrations, with relaxed scrutiny as a means of providing speed. Continuation of present practices which in our opinion comprise a "rubber stamp" approach to pesticide reviews, will exacerbate, rather than improve, our future pesticide problems. The RPAR process - the process of intense examination of "the worst first" - is in disarray. Relaxed safety standards, not yet made public, have been applied in closed-door meetings with pesticide manufacturers. Pesticides whose risks were exhaustively examined for years are now being hurriedly given a clean bill of health. We are fearful that those pesticides that the Administration unjustifiably removed from the RPAR list in the past two years will provide the pesticide horror stories of the future.

The Administration has also recently proposed regulations which will substantially weaken health and safety standards for new registrations. Thus we are witnessing a shift from an 11 year history of inaction to speedy but misdirected action. Neither approach is acceptable. Both approaches only perpetuate the use-first, regulate-later pattern that has caused serious problems in the past and continues to do so today.

SIX CHANGES IN FIFRA THAT ARE NECESSARY TO IMPROVE PROTECTION OF THE PUBLIC AND THE ENVIRONMENT IN THE COMING YEARS

In addition to the reregistration problem discussed earlier, the following is a description of six critical areas where we believe FIFRA must be changed to achieve a reasonable balance in protecting the public and the environment from pesticide hazards. This list is not an exhaustive survey of the amendments we are proposing, but highlights key areas of concern based on 11 years of experience with the present Act.

I. FIFRA SHOULD BE AMENDED TO ASSURE FULL PUBLIC PARTICIPATION IN PESTICIDE DECISIONMAKING AT THE EPA.

Controversy about closed-door negotiations and secret deals between the EPA and the industry which it regulates have been raised before Congress and the nation in recent months. Of even greater concern to us, however, is the fact that the public has been severely hampered, if not entirely blocked, from participating much as by Agency bias.

The current Act, for example, requires notice to the public of pending pesticide registration applications and the opportunity for public comment. But, the "right" to comment is a sham since EPA is not required to disclose the safety tests that form the basis of the application until thirty days _after_ the decision is made, when no further comment opportunity exists.

The present Act also provides pesticide companies with an administrative appeal if a registration application is denied, or a pesticide is cancelled or suspended. Yet, no such right is provided to the public when the application is granted, or when EPA decides to continue a registration after the review process is completed.

Two amendments are necessary. One would make the data submitted in support of an application available at the time that public comment is sought, that is, at the time the application is filed. The other would permit a member of the public to request an administrative hearing when the registration review process is completed.

In recent months, we have learned of a pattern of closed-door meetings between EPA and chemical industry officials. At these so-called "decision conferences," established by Dr. John Todhunter, the former Assistant Administrator for Pesticides and Toxic Substances, agreements have been reached on the content of Registration Standards, on whether RPAR has been properly triggered, and on the final result of the RPAR health and safety decisionmaking process. In our view, such procedures transform the regulated industry into the regulator, and may well violate the current Act.

Section 3(c)(8), the so-called Grassley-Allen amendment of 1978, is cited by EPA as authority for the closed-door meetings. The amendment provides that the Administrator may not commence the RPAR process "unless such ... process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or the environment." On its face, this is a reasonable provision. But EPA has read the legislative history of this provision to mean that the Agency has the burden of considering the extent of human and environmental exposure to pesticides prior to initiating the RPAR process. It also is being used to justify closed-door meetings with industry in analyzing these sensitive health issues. In this context, Senator Leahy's remarks in the 1978 Conference Report are relevant, because they explicitly rejected "private or closed door negotiations" or "protracted and secret discussions of risk and benefits." H. Conf. Rpt. 95-1560, 95th Cong. 2d Sess. (1979).

When the RPAR process was established, the rebuttable presumption was triggered for chronic toxicity by evidence concerning the risks of the pesticide alone. Thereafter, the registrant was required to rebut the presumption by demonstrating that human or environmental risks were very small or that the pesticide's benefits exceeded its risks. As a consequence of the Grassley-Allen amendment, EPA has not added any new products to its list of RPAR candidates in the last two years, and it has issued only a very few RPAR notices for products on the old candidate list. In addition, EPA has even moved to rebut its own presumptions for previously issued RPAR notices, without waiting for the registrant to do so.

The Grassley-Allen amendment, at least as interpreted by EPA, has placed an unnecessary and onerous burden on an already understaffed agency. In addition to determining the toxic effects of chemicals, EPA must also amass evidence about the full extent of exposure to the pesticide. While it may arguably be appropriate not to initiate the RPAR process for acutely toxic pesticides in the absence of exposure evidence, the law places the burden of demonstrating the safety of a pesticide with chronic toxicity (including the burden of estimating risk on the basis of exposure) squarely on the registrant. To the extent that the Grassley-Allen amendment has resulted in an unintended shifting of the burden to EPA, the law should be clarified to reaffirm that the registrant has a continuing burden to establish the safety of a pesticide.

Finally, public access to the underlying safety tests remains difficult to achieve due to vague and ambiguous qualifications on "delivery" of data to multi-national pesticide producers. This provision has been used by industry in seeking to prevent publication of cancer studies for purposes of peer review - an essential process, especially in light of the IBT fraudaulent research scandal. Yet, it has not been demonstrated that potential harm in non-patent countries outweighs the need for widespread and routine peer review of industry tests by the public and the independent scientific community. As long as §10(g) remains in the Act, it will take a lawyer, and many months, for a citizen to obtain "access" to safety tests. Although the constitutionality of the disclosure provisions of FIFRA is currently at issue, we are confident that the law will be upheld. Thus, we urge the Subcommittee to address the practical problems confronting persons seeking access to the data.

II. FIFRA SHOULD BE AMENDED TO CLOSE LOOPHOLES USED SYSTEMATICALLY BY PESTICIDE COMPANIES TO MARKET INADEQUATELY TESTED PESTICIDE PRODUCTS.

The purpose of the reregistration process was to deal with "old" pesticides. EPA's second critical job under the 1972 and later amendments was to develop a comprehensive system for full review of future pesticides. This system was embodied in §3 of FIFRA. Under §3, there are several routes to register a pesticide:

- full registration, under §3(c)(5)
- conditional registration, under §3(c)(7)
- experimental use permits, under §5
- emergency exemptions, under §18
- special local needs registration, under §24(c)

Whenever anything less than full registration under §3(c)(5) is initially used, FIFRA contemplates that full registration under §3(c)(5) will occur expeditiously, except in the narrow special local needs category. Only under §3(c)(5) registration, when the full panoply of health and safety test requirements are applicable, can public health be fully protected.

The December 1982 Staff Report by the House Subcommittee (pp. 36-52) documents the extent to which this system has been avoided through abuse of the "emergency" exemption authority of §18 and the special local need exemptions of §24(c). From 1978 to 1982, annual emergency exemptions have grown from 165 in 1978, to 727 in 1982 - an increase of 430%. In 1980, 39% of all emergency exemption requests were not granted; in 1982, the number had dropped to 7%. Two pesticide company officials were recently quoted as proudly trumpeting their ability to manipulate the registration process by "pulling out all the stops" to gain a §18 exemption. (Dec. 82 House Subcommittee Staff Report, (p.58), Memo of Ed Johnson, Director of the Office of Pesticide Programs, EPA, dated Sept. 23, 1982).

The first solution we recommend is to close the conditional registration pipeline (except for "me too" pesticides) until reregistration is completed. No new major testing requirement has been imposed by the EPA since 1972. The industry has been aware of its invalid tests (IBT) problems at least since 1977. No test requires more than three years to complete. In our opinion, pesticide companies have no excuse, at this time, to seek additional pesticide registrations without providing the full package of health and safety tests which enable EPA to evaluate the hazards of a product. Moreover, the Agency should not spend limited resources evaluating new but incomplete applications, when it has failed to meet its statutory duty to review (reregister) old "grandfathered" pesticides under current standards.

The second solution is to stop the granting of exemptions for bogus emergencies by tightening the §18 "emergency" requirements. One example of a recent abuse of this process, not discussed in the December 1982 House Subcommittee Staff Report, was the registration of Larvadex, used in chicken feed to create manure toxicity to housefly larva. Larvadex residues also are found in the eggs and chicken meat. The point is that this highly controversial chemical is in use in 20 or more states, based on emergency exemptions. This case of the "house fly emergency" demonstrates how loose the current standards for granting such "emergency" registration have become. FIFRA should be amended to state a precise and narrow definition of what constitutes an "emergency" sufficient to justify use of an unregistered pesticide.

The third solution is to amend §24(c) to stop the national marketing of pesticides under the "special local needs" provisions of FIFRA. The December 1982 House Subcommittee Staff Report (p.51) demonstrates that pesticide registrants have widely taken advantage of the special local needs registration program to market pesticides throughout the country, state by state, as special local needs. Eighty-one pesticides have recorded 15 or more special local needs registrations, with Permethrin topping the list at 353. This end-run method of obtaining pesticide registrations enables avoidance of the federal testing requirements under §3(c). FIFRA should be amended to require strict EPA scrutiny of §24(c) registrations, and require §3(c)(5) registrations where there is no truly special or local need. A strong presumption against such registration should be triggered when multiple states are involved.

III. REGISTRATION REQUIREMENTS SHOULD GIVE SPECIAL CONSIDERATION TO PESTICIDE EXPOSURE OF HUMANS, ESPECIALLY CHILDREN.

Human safety standards used in the registration process should also recognize that many young children work in agriculture. The Fair Labor Standards Act (FLSA) permits children 12 or older to work in agriculture. It was recently amended to allow 10 and 11 year old children, under limited circumstances, to work so long as a standard of stringent pesticide safety can be met. 29 U.S.C. §213(c)(4)(A)(iii). The Secretary of Labor has ruled that that standard cannot be met because of the paucity of scientific data regarding pesticide vunerability of young children. The data that do exist document the particular vulnerability of children. This, the Secretary of Labor's action was responsive to an "EPA warning that it had no standards that could safely be applied to child harvesters and no data on which to base such standards." Washington State Farm Bureau v. Marshall, 625 F.2d 296, 303 (9th Cir. Ct. of Appeals, 1980).

While the FLSA protects 10 and 11 year old children, FIFRA is silent regarding children 12 and above. There is every scientific reason to believe that a 12 year old is just as vulnerable as an 11 year old. FIFRA should be amended to protect these children.

The standard for adults should similarly be reexamined and altered. The present test for registration balances risk of both human and environmental damage with benefits of pesticide use. In our view, the balancing test should remain for environmental damage, but risks to human beings should not be traded off by benefits. For such risks, the more stringent "will endanger humans" standard used in §211 of the Clean Air Act will allow EPA to better protect human life.

In addition, EPA should be required to initiate cancellation proceedings against a pesticide when a substantial question of safety arises concerning that pesticide. Therefore, §6 should be amended to require EPA to initiate cancellation proceedings by issuing a notice of intent to cancel when the Agency determines that the pesticide "may reasonably be anticipated to endanger" human health.

IV. FIFRA SHOULD BE AMENDED TO ASSURE BETTER PROTECTION FROM MISUSE OF PESTICIDES.

A. Transfer of Farmworker Jurisdiction to OSHA

FIFRA ought to be amended so that farmworker safety regulations are adopted and enforced under the Occupational Safety and Health Act (OSHA).

OSHA has as its primary mission the protection of our nation's working people. The OSHA Administration has developed expertise in the area of occupational safety and health.

FIFRA, by comparison, is a licensing statute; occupational health is not its primary or even secondary concern. EPA lacks both expertise and experience in the area of occupational safety and health.

The OSHA Act standards concerning toxic substances require "the attainment of the highest degree of health and safety protection for the employee." 29 U.S.C. §655(b)(5). The Supreme Court has interpreted this provision to "require the elimination, as far as reasonable, of significant risks of harm." I.U.D., AFL-CIO v. American Petroleum Institute, 48 U.S.L.W. 5022, 5031 (July 2, 1980). In comparison, FIFRA's regulatory standard provides much less protection for workers. It is a classic product regulation statute and requires a cost-benefit analysis of a product's "unreasonable risk(s) to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."

OSHA requires employer measurement of exact exposure levels of toxic substances while EPA only regulates 12 pesticides for reentry time periods of 24-48 hours. Employers are not required under FIFRA to measure exposure levels at all.

OSHA requires many other worker protections which FIFRA does not require, such as detailed medical surveillance, employee information and training, respirators and replacement of protective clothing, and safeguards against employer retaliations.

In addition to standard-setting, OSHA's enforcement procedures are superior to EPA's: OSHA can enforce its standards directly; EPA may enforce only indirectly for failure to comply with label instructions. OSHA also has a detailed inspection, complaint, and enforcement system.

There is no rational reason why farmworkers, unlike all other American workers, are denied OSHA protection against toxic chemical dangers.

B. Amend FIFRA to Require States to Enact Enforcement As Stringent as Federal Law Prior to Receiving Primary Enforcement Authority.

Congress should amend §26 of FIFRA to require that before EPA grants a state primacy in enforcement authority, that state must pass laws which are at least equivalent to or more stringent than FIFRA. The OSHA and many other federal statutes grant a state the right to enforce its own laws if its state plan is equal to or more stringent than the federal law. There is no good reason why FIFRA should be any less protective.

Unfortunately, there has not been even minimally effective enforcement of these laws. (*See* Government Accounting Office Report, "*Stronger Enforcement Needed Against Misuse of Pesticides*" (Oct. 1981)). Therefore, the Congressional intent to protect man and the environment from pesticide misuse has not been accomplished. One step toward that goal would be to set a federal floor under state-enforced use restrictions.

V. FIFRA SHOULD BE AMENDED TO ASSURE ADEQUATE AGENCY RESOURCES BY REQUIRING PESTICIDE INDUSTRY REGISTRATION FEES TO COVER THE FULL COST OF REVIEWING INDUSTRY DATA.

FIFRA should be amended to make the registration process pay for itself. Such a change would be consistent with the long-standing Congressional policy of charging full cost for pesticide residue tolerance reviews by EPA. *See* 21 USC §346(c). As Congress explained in 1954 when this policy was established:

> "It is reasonable that the cost of this service, so far as practicable, should be borne by the applicant for the tolerance. From the service, the applicant derives the benefit of independent and departmental scientific review of the data compiled to

> establish the safety of the proposed residue tolerance. This should tend to avoid any possible harmful effects from use of the manufacturer's products, and is a legitimate charge to the cost of doing business." Sen. Rpt. No. 1635, 83rd Cong., 2d Sess.

The fiscal crunch in the past several years has necessitated a 29% reduction in EPA's pesticide program staff. There is little reason to believe that the fiscal constraints will significantly ease in this decade. For this reason, the present Administration has proposed user fees for many federal services. Pesticide registration should be a prime candidate.

VI. FIFRA SHOULD BE AMENDED TO PROVIDE A PRIVATE RIGHT OF ACTION.

FIFRA should be amended to include a private right to sue for violations of the Act.

First, in regard to enforcing FIFRA and state pesticide laws, the states and EPA have been extremely lax. The General Accounting Office Report, "Stronger Enforcement Needed Against Misuse of Pesticides" (Oct. 1981), documents this problem.

Second, the EPA 1984 budget request seriously limits both EPA's and the states' manpower and financial capability to enforce pesticide laws.

A private right to sue does not require citizens to beg EPA or their state governments to help them. It allows a victim to bring suit directly against FIFRA violators. In an era of declining government regulatory enforcement, it is only fair to give the private citizen the right of self-protection.

Third, the rate of pesticides injuries has been increasing as the rate of pesticide usage increases. The EPA Pesticide Incident Monitoring System has received over 55,000 pesticide injury incident reports over the past several years. These reports show an increase in incidents over the years. Meanwhile, pesticide production in this country has increased from 200,000 pounds in 1950 to over 1.7 billion pounds in 1980. As long as this trend continues there is little doubt that more and more Americans will suffer pesticide-related injuries. Some means must be found to stop involuntary pesticide poisoning. Providing citizens a private right to sue is a small step in the right direction.

Conclusion

Over the past seven years, many serious problems in EPA's implementation of FIFRA have been identified in Senate, House, and GAO reports. As described above, the areas of concern include the adequacy of EPA's health and safety reviews of pesticide registration data and the extensive granting of emergency and special local needs registrations which circumvent the basic registration requirements of §3. The investigative reports also document deficiencies in EPA's laboratory audit program; the need for overhaul of the tolerance setting process; and the apparent adoption by EPA of a much less protective approach to assessing the cancer risk posed by certain pesticides.

All of these issues raise potentially serious public health questions which should be addressed by this Subcommittee now rather than in 1985. The Subcommittee does not need two more years to identify the issues and to consider remedial legislation. The urgency of the problems and the potential adverse effects on public health that may result from continuation of the status quo are persuasive reasons for the Senate to act this year to address them. The House has passed only a one-year reauthorization and is committed to considering appropriate legislative changes on an expeditious basis. We urge the Subcommittee to take a similar course and to proceed directly to consideration of corrective amendments to FIFRA.

(The following summary of the Harpers Ferry bill was inserted by Jacqueline M. Warren of the Natural Resources Defense Council)

Executive Summary of the Harpers Ferry (Labor, Environmental, Consumer), Bill to amend the Federal Pesticide Law (FIFRA).

This bill proposes amendments to the federal pesticide law (FIFRA) which will:

I. Assure full public participation in EPA decisionmaking, and block secret industry-agency meetings;

II. Assure adequate agency resources by requiring pesticide industry registration fees to cover the costs of reviewing industry data and issuing licenses;

III. Close loopholes used by the pesticide companies to market untested or partially tested products;

IV. Require special agency review of pesticides which contaminate food and water;

V. Assure that farmworkers receive adequate protection.

Section-by-Section Analysis of the Harpers Ferry (Labor, Environmental, Consumer), Bill to amend the Federal Pesticide Law (FIFRA).

Introduction.

During the eleven years since the last major Congressional action on pesticides, it has become clear that federal law governing pesticides is seriously flawed. Tens of thousands of workers have been poisoned, consumers are forced to eat food contaminated with residues of pesticides linked to birth defects, cancer, and sterility, and widespread contamination of drinking water supplies is just now being discovered. EPA, under both Democrats and Republicans, has been paralyzed by numerous unworkable provisions of the federal act, lack of resources, and industry resistance. The program of reviewing new and existing registrations under current standards, which was to be completed in October, 1977, remains in shambles today. Hundreds of industry-submitted safety tests have been invalidated due to inaccurate, shoddy and allegedly fradulent work by the largest industry-supported safety testing lab, and industry credibility has sunk to a new low. Meanwhile, the public and independent scientists have been blocked from access to safety data and from participation in the agency's decision-making processes.

A coalition of workers, environmentalists, consumers, and others has come together to support a major pesticide law reform package before the 98th Congress. The coalition members are committed to reforming FIFRA into a law that works to protect public and worker health, the environment and the interests of agricultural producers. The current law has primarily supported the interests of large pesticide producers, drowned the agency in a sea of red tape, and created an elaborate facade of regulation for public consumption.

The attached draft FIFRA bill contains amendments to the existing law. This summary explains the purpose and intent of each amendment in sequence as it appears in the Act.

Section 2(a). New definition of "active" ingredient.

The Act currently distinguishes between "active" and "inert" ingredients. "Active" ingredients are defined as those that are designed to kill or mitigate pests; "inerts" are the other chemicals in a pesticide mixture. Although "inerts" may not be targeted to effect the pest, the "inert" may be equally or more dangerous to humans than the "active" ingredient that affects the pest. Nevertheless, the agency has regulated pesticides as if "inerts" were inert to humans, which is not the case, by exempting inerts from regulatory scrutiny. This amendment establishes that toxicity to humans, rather than pests, is the trigger requiring regulatory scrutiny by the agency. It further assures that supporting data on toxic inerts is available to workers and the public under Section 10.

Section 2(e). Actual applicator of restricted pesticide must be certified. §2(e) and 3(d)(1)(C)(i).

Current law requires applicators of "restricted" (more toxic) pesticides to be certified. It allows non-certified persons to actually apply the pesticides while "under the supervision" of the certified applicator, although the certified applicator need not even be present at the application site. This amendment strikes the indirect supervision loophole. Since the Act has permitted a very broad and simple certification process, the loophole can be removed without disruption.

Section 2(g). Definition of "misbranded." Change to require a more comprehensive warning on labels.

EPA has determined that some pesticides now in use cause cancer, birth defects, reduced sperm counts and other diseases in animals, and may cause such effects in humans, but it has allowed use of such pesticides to continue. Although the agency has at times considered placing warnings of such effects on the label, it has not adopted a policy requiring such warnings. This amendment requires such warnings.

Section 2(bb). Definition of "Unreasonable adverse effects on man and the environment" changed to distinguish between humans and the environment.

Under current FIFRA, the operative standard for registration and cancellation is the prevention of unreasonable adverse effects on man and the environment. This will remain the test for pesticides that pose risks only to the environment. For pesticides that pose risks to human beings, the test will be the more stringent "will endanger" test taken from section 211 of the Clean Air Act as interpreted in Ethyl Corp. v. EPA, 541 F.2d 1 (D.C. Cir. 1976) the "will endanger" test will allow the agency to act on the basis of risks alone without a strict comparison with benefits.

Section 2(gg). Definition of "data gap."

The term "data gap" is defined for purposes of reregistration to clarify an ambiguity that has plagued EPA for many years. EPA has always defined "data gap" to mean the complete absence of a study necessary to support the registration of a pesticide. The new definition offered here would add to the definition instances in which there are studies in EPA's files, but those studies are not capable of supporting the registration of the pesticide that they purport to support. When combined with the new language on reregistration in Section 3(g), this new definition will require EPA to examine and validate each study prior to reregistering the pesticide.

Section 2(hh). Define "emergency."

EPA appears to be defining "emergency" in an ad hoc fashion in administering Section 18's emergency use exemption provisions. Under EPA's current broad definition, the number of emergency use exemptions that the agency has granted has increased dramatically. The new amendments would define "emergency" narrowly to include only true emergencies threatening public health or economic harm to at least a significant portion of the general public.

Section 3(c)(2)(A). Registration data requirements to be adequate, and consistent.

The administration is currently proposing to change pesticide registration data requirements in a manner that (1) weakens the data requirements, and (2) allows secret agreements between pesticide companies and the agency to change such requirements on a case by case basis. Those amendments require the adoption of data requirements by guidelines, which are adequate for the agency to evaluate pesticides under the standards of the Act. In addition, they set strict limits on waivers of data requirements and put all such activities on the public record.

Sections 3(c)(2)(A), 3(c)(4) and 3(c)(5). Public right to participate in registration decisions established.

Under current law the public is effectively blocked from participating in agency decisions to register a pesticide. Although the Act now provides for public notice of impending registration decisions, the agency is not required to make the safety tests which form the basis for the decision available to the public until 30 days after the decision is made. These amendments clear up this ludicrous situation by (a) assuring that the public can see the safety studies during the comment period, (b) extending the comment period to 90 days, and (c) providing a clear right of appeal if the agency registers a pesticide over public objection.

Section 3(c)(2)(B)(i). Public notice of Reregistration Requirements.

The Act currently requires EPA to provide a list of registrants subject to additional data requirements to any interested person. The amendment would require the agency to publish in the Federal Register a list of registrants and a list of the requirements. This will allow the public to inform itself of exactly what information is lacking among the studies supporting the registration of a pesticide. In addition, the new section makes explicit reference to the section 3(g) reregistration requirements.

Section 3(c)(2)(B)(iv). Suspension of Pesticides for Failure to Adhere to Section 3(g) Timetable.

Section 3(c)(2)(B)(iv) presently allows EPA to suspend the registration of a pesticide when a registrant has been dilatory in responding to a new data requirement. New section 3(c)(2)(B)(iv) requires the agency to suspend the registration when either the Administrator or the registrant fails to comply with the new deadlines explicitly incorporated into section 3(g).

Section 3(c)(5). New Test for Registering Pesticides.

New section 3(c)(5)(E) adds a requirements that prior to registering a pesticide the Administrator must find that it will not endanger humans. This separate test for risks to humans is taken from section 211 of the Clean Air Act and is intended to allow the agency to act on the basis of risks alone without a strict comparison of risks or benefits. In addition, section 3(c)(5)(E) explicitly requires the agency to consider effects on children who are permitted to work in pesticide treated areas pursuant to provisions of the Fair Labor Standards Act.

Section 3(c)(5). Efficacy Data Waivers on a Case-by-Case Basis Only.

Under the current law the agency may waive efficacy data requirements. A new amendment to this section would delete this option.

Section 3(c)(5). Change Standard to Require Administrator to Consider Specific Environmental Effects.

The current statute allows the Administrator to register a pesticide if he finds that it will not generally cause unreasonable adverse effects on the environment. There have been suggestions that the word "generally" allows the Administrator to ignore adverse effects on specific populations or subpopulations. While we do not agree with this interpretation of the statute, it should be amended to exclude this argument in future cases involving effects on small populations. The Section 6 standard for cancelling a pesticide should likewise be amended.

Section 3(c)(5). Provide for Hearing at the Request of Any Interested Person for Decisions to Register New Pesticides.

The current Act manifests an anomolous assymetry. Potential pesticide registrants are entitled to a hearing on the Administrator's denial of a registration, but persons who might be harmed by the introduction of a new pesticide into the environment may not request a hearing on a decision favorable to the registrant. This is both unfair and inefficient.

It is unfair, because it gives pesticide proponents a procedural right that it denies to those more concerned with the safety of pesticides than with their profitability. Since Section 6 hearings are very burdensome and expensive, pesticide proponents can use the threat of Section 6 hearings as leverage on the agency. Those opposed to the use of a pesticide have no counter-leverage.

It is inefficient because ultimately it forces those opposed to the use of a pesticide to proceed immediately to federal district court to seek review of the decision to register. Since there would have been no hearing and no record, the judicial review would apparently be de novo. It would be inefficient to force all of the parties to undergo a trial in a federal district court before the agency had an opportunity to consider the facts and arguments of those opposed to a pesticide's registration.

Section 3(c)(5). Registration standards amended to strengthen protection of humans, with special provisions for children farmworkers.

The registration criteria of Section 3(c)(5) determine which pesticides are registered for use, and which are rejected. The Act currently prohibits registration of pesticides which "generally cause unreasonable adverse effects on the environment" when used "in accordance with widespread and commonly recognized practice." This bill splits this provision into two standards, one for the environment, and one for humans. The environment section remains the same, except that the word "generally" is stricken. This is to clarify that unreasonable adverse effects on one area of the country, or one area of the environment are sufficient to block registration.

The standard for humans is the "will endanger" standard explained in connection with section 2(bb).

The standard for humans requires special consideration of children who work in agriculture. The Fair Labor Standards Act (FLSA) permits children 12 or older to work in agriculture, and thus become exposed to pesticide residues. Children are more vulnerable to pesticides, because they are smaller. Toxicology recognizes this obvious truth by expressing the toxicity of pesticides in milligrams (of pesticide) per kilograms (of bodyweight). Nevertheless, the agency has neglected to establish pesticide standards which consider the presence of children in the fields. This issue was recently reviewed by two circuit courts in litigation involving 10 and 11 year olds under a special amendment to the FLSA. This bill clarifies the intent of Congress to assure protection of the health of all such children.

Several additional provisions of current law are stricken in this section.

(1) The "lack of essentiality" clause restricts the Administrator's discretion to reject pesticides that are not needed. It is stricken here.

(2) The "two or more pesticide" clause also seeks to limit agency discretion to reject less useful pesticides. It is also stricken, but with the understanding that the law would permit several pesticides to be available to control a single pest, since IPM, and combatting resistance, may require the availability of several chemicals.

Section 3(c)(7). Conditional registration abuses halted.

Under current law, there are several routes to register a pesticide so that it can be sold in the United States. These are:

(1) Full registration 3(c)(5)

(2) Conditional registration 3(c)(7)

(3) Experimental use permit 5

(4) Emergency registration 18

(5) Special local needs registration 24(c).

Congress intended that all registrations eventually occur under full registration, where complete testing is evaluated by EPA, except under the narrow special local needs category. The pesticide industry however, has not performed the required tests for full registration for most pesticides. Instead it has used the other routes, especially conditional, emergency, and 24(c) registrations to circumvent the normal testing requirements. Use of these loopholes has increased during the current administration, and clearly violate the intent of Congress. This bill closes each such loophole. The explanations are set forth under the appropriate sections, below.

Under current law, conditional registration is provided for three situations: "me-too" registrations, new uses of existing chemicals; and new chemicals. No new major testing requirement has been imposed by the EPA since 1972. The industry has been notified of its invalid test (IBT) problem since 1977. No test requires more than three years to complete. Pesticide companies have no excuse, at this time, to seek additional pesticide registrations without providing a full testing package which enables the EPA to evaluate the hazard of the product. Moreover, the agency should not spend resources evaluating these new, incomplete applications, when it has failed to meet its statutory duty to review (reregister) old grandfathered pesticides under current standards

This bill eliminates from eligibility those pesticides which have a rap sheet (prior suspension/cancellation or voluntary withdrawal for health or environmental reasons). Also proposed is a requirement to make available to the public the data submitted and the timetables for filling data gaps on conditional registration applications.

Section 3(c)(7). Public Availability of Data in Support of Conditional Registration and Timetables.

A new amendment to the end of section 3(c)(7) would require the agency to make studies submitted in support of conditional registration available to the public and require the agency to provide the public with timetables for completion of studies necessary for a full section 3(c)(5) registration. This self-explanatory amendment is necessary so that outsiders can monitor the conditional registration process.

Section 3(c)(8). Repeal Section 3(c)(8) (the Grassley-Allen Amendment).

Section 3(c)(8), the so-called Grassley-Allen Amendment of 1978, provides that the Administrator may not initiate an interim review process (the RPAR process) "unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or the environment." The EPA has read this requirement and its legislative history to require that the agency consider the extent of human and environmental exposure to pesticides prior to initiating the RPAR process. Previously, the rebuttable presumption was triggered for chronic toxicity by evidence concerning the properties of the pesticide alone. The registrant was required to rebut the presumption by demonstrating *inter alia* that human or environmental exposure was so small as to demonstrate that the pesticide's benefits exceeded its risks.

As a result of the Grassley-Allen Amendment, EPA has not added any new products to its list of RPAR candidates in the last two years and it has issued rebuttable presumption notices for only a very few of the products on the old candidate list. In addition, EPA has commenced to rebut its own presumptions for previously issued RPAR notices without waiting for the registrant to do so.

The Grassley-Allen Amendment has placed an enormous burden on an understaffed agency. In addition to determining the toxic effects of chemicals, it must also gather evidence of actual exposure to the pesticide. While it is appropriate not to initiate the RPAR process for acutely toxic pesticides in the absence of exposure evidence, it is also appropriate to place the entire burden of demonstrating the safety of a pesticide with chronic toxicity (including the burden of estimating risk on the basis of exposure) on the registrant. The proposed Bill would repeal the Grassley-Allen Amendment.

Section 3(d). Add Contamination of Ground Water as a Reason for Classifying a Pesticide for Restricted Use.

It is becoming increasingly apparent that pesticides have been contaminating groundwater. Because groundwater contamination can result in direct adverse health consequences, pesticide applicators should be trained in how to avoid groundwater contamination.

Section 3(c)(d). Application of Restricted Use Pesticides Only By Certified Applicators.

Under current law restricted use pesticides may be applied by an uncertified applicator if he or she is applying the pesticide under the supervision of a certified applicator. The new amendment would strike "or under the direct supervision of" so as to allow restricted use pesticides to be applied only by certified applicators.

Section 3(f)(1). Registration of Unreregistered Pesticides Not Prima Facie Evidence of Compliance.

Currently the statute provides that registration, by itself, is not a defense for the commission of any offense under the Act; except that registration shall be prima facie evidence of compliance with the registration provisions of the Act. Since pesticides that have not been reregistered are demonstrably not in compliance with the registration provisions of the Act (since 1972), the amendment would limit the prima facie evidence of compliance to pesticides that have been registered or reregistered since October 21, 1972.

Section 3(f)(2). Consultation with States.

The amendment would allow EPA to consult with states as well as with other federal agencies in connection with an application for registration.

[Note: This may not be a good idea, because it would appear to sanction what might otherwise be a violation of the Federal Advisory Committee Act. Our position in this will depend upon whether we think the outcome of such consultations is likely to be beneficial.]

Section 3(g). Incorporate Explicit Timetables for Reregistration.

In 1972 Congress required that all pesticides be reregistered in accordance with modern scientific protocols. Congress intended for EPA to examine the data in its files for each pesticide and to require registrants to perform such studies as were necessary to justify their registrations under modern requirements. The ultimate goal was for the data supporting the registration of previously registered pesticides to equal in quality the data supporting the registration of new pesticides registered under modern health and environmental standards. Congress originally established a deadline of October 21, 1975 to achieve this goal. The deadline was later extended to October 21, 1977.

The EPA utterly failed to implement the Congressional mandate. EPA first determined that it was not necessary to examine the validity of the old studies in deciding which data gaps were to be filled. The IBT scandal and other internal EPA investigations revealed that the assumption that existing studies were valid was erroneous. The agency then began the much larger task of reexamining the scientific basis for all previously registered pesticides. EPA asked Congress for an indefinite extension of the reregistration deadline.

In 1978 Congress eliminated the explicit reregistration deadline. Instead, Congress told EPA to accomplish the reregistration of all pesticides "in the most expeditious manner practicable" and told the agency to give top priority to pesticides that result in postharvest residues on food or feed crops.

Once again, the agency has failed to implement the Congressional goal. Far from attempting to accomplish re-registration "in the most expeditious manner practicable" the agency has shifted resources out of the reregistration program and into the registration program. The agency has proceeded at a snail's pace with its administrative registration standards program, which is intended to gather together the information that the agency has active ingredients and to identify data gaps for reregistration purposes. Moreover, it is not at all clear that the agency is giving top priority to pesticides that result in postharvest residues on food and feed crops.

While the "registration standard" idea is basically sound, it is clear that the agency will not implement the Congressional reregistration goal unless it is once again subjected to specific deadlines. The statutory language suggested here would prescribe a four-step phased program with specific deadlines designed to bring about the reregistrations of all pesticides within seven years and three months after the enactment of the proposed legislation. The better part of a decade is surely ample time to accomplish this obligation, which has already been part of EPA's job description for more than a decade.

Unlike previous legislation, the proposed Bill would seek to encourage the active participation of registrants in the reregistration process by requiring that the registrations of pesticides be suspended if the Administrator and registrants do not act expeditiously in accordance with the specific timetable. We believe that this accords with the fundamental policy underlying the Act that the burden of demonstrating a pesticide's safety is at all times upon the registrant. Those pesticides for which data gaps exist have not been shown to be acceptably safe. The legitimacy of the registrations for these pesticides is in question until the data gaps are filled and until old invalid studies are replaced with scientifically sound studies. The deadlines in the proposed Bill are an attempt to implement this basic policy.

Section 4. Use of Restricted Use Pesticides: Certified Applicators.

Currently, the Administrator is charged with the establishment of standards for the certification of pesticide applicators. The standards must insure the competency of the applicator in handling pesticides for which certification is issued. These standards are rendered meaningless, however, by limiting provisions which (1) prohibit the compulsory administration of a written competency exam; and (2) allow an applicator to complete a certification form as evidence of requirements sufficient to meet the standards. These forms must include "adequate information to carry out the intent of the Act," but do not require proof that the applicant has completed an approved training program.

The Amendments strengthen the ability of the Administrator to regulate the certification of applicators by deleting limits on the Administrator's certification program and the certification form as alternative proof of qualification.

Section 5. Changes to EPA's Experimental Use Permitting Authority.

It is becoming increasingly apparent that experimental use permits (EUPs) are being issued by EPA somewhat indiscrimnantly. In at least one case it appears that EPA has allowed an EUP to substitute for Section 3 or Section 18 registrations.

For example, EPA granted an EUP to the Fish and Wildlife Service on October 4, 1982, authorizing the use of single lethal dose 1080 baits on over 180,000 acres in three states. It is clear that the FWS 1080 research authorized under the October 4 EUP was inadequate to determine efficacy of the chemical in the proposed delivery system. This problem is acknowledged by Herbert Harrison of the Registration Division in his cover letter granting the EUP:

> "While we recognize the practical difficulties associated with attempting to limit predator control efforts over wide areas where people earn livelihoods from raising livestock, it is unlikely that a useful answer will ever be obtained concerning the effects of baiting on the need for other controls if these controls are not withheld. Furthermore, the 'relationship between baiting and other controls' cannot be studied unless experiments evaluating each method individually are part of the whole research picture."

The new amendment explicitly requires the applicant for an EUP to design studies that will generate data required for a Section 3 registration. This will force EPA to make more rigorous analyses of the requests and to grant only those permits which are likely to produce useful and reliable data.

Efficacy data should be required for pesticides examined under EUPs. As noted earlier, EPA has not diligently examined the effectiveness of pesticides in comparison to the risks, although Section 3(c)(5)(A) of FIFRA directs the Administrator to register a pesticide if "its composition is such as to warrant the proposed claims for it."

There is a logical process for registering pesticides which has been convoluted by EPA in recent efforts to circumvent Section 3 of FIFRA. The proposed new language prohibits the issuance of EUPs for testing chemicals for which registration is pending under Section 3 or 18. The first step should be the granting of the EUP, followed by registration only after the results of the studies are evaluated.

Finally, once a pesticide has been cancelled, suspended or voluntarily withdrawn for health or environmental reasons, an experimental use permit would not be allowed for that pesticide unless no other pesticide or practices are available to control pest damage.

Section 6. Require Issuance of Cancellation Notice for Pesticides That May Cause Significant Adverse Effects on Humans.

Section 6 would be amended, reflecting the amendment of section 3, to incorporate a "will endanger" standard for humans. The notice of intent to cancel should be issued when the Administrator determines that a pesticide may reasonably be anticipated to endanger humans. This is not intended to depart from the "substantial question of safety" test articulated by the D.C. Circuit in Environmental Defense Fund v. Ruckelshaus, and language should be included in the legislative history to reflect this fact. The purpose of this change is merely to reinforce upon a reluctant agency its duty to protect public health. To further reinforce this obligation, and to make it enforceable in court, the word "may" is changed to "shall."

Section 6(b). Allowing Members of the Public to Demand a Hearing When the Administrator Issues a Notice of Intent to Cancel a Pesticide.

The Chlorobenzilate case held that environmental groups and other interested members of the public have no right under the current statute to demand a hearing when a notice of intent to cancel does not go far enough. This allows EPA and registrants to make sweetheart deals at the end of the RPAR process and in essence to shut the public out of the real decisionmaking process. The amendment would remedy this by explicitly giving members of the public without an economic interest in a pesticide the right to demand a hearing when EPA issues a notice of intent to cancel.

Section 6(b). Registration of Previously Cancelled Pesticides.

Currently, EPA addresses previously cancelled pesticides by regulation. The statute is silent on the matter. EPA has recently taken disturbing positions in proceedings related to the pesticides mirex and 1080 that demonstrate that the statute should address previously cancelled pesticides directly.

The amendment would increase the burden for registration so that it would be difficult to bring cancelled pesticides back into use simply for political purposes. The obvious example is 1080, which was promised to the livestock industry by the Reagan Administration, even though livestock losses have not increased since use was discontinued, alternatives are available, and there is no data demonstrating that 1080 is effective in reducing livestock losses.

To facilitate this change, Section 6(d) would be amended to specifically require that the scope of registration hearings be limited to the examination of new information. This provision would discourage the reconsideration of prior cancellation orders.

Section 10(d)(1)(C). Allow Disclosure of Inert Ingredients.

Currently, inert ingredients are not required to be disclosed to the public unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment. Even a sympathetic Administrator would have difficulty making this determination. Indeed, since this is the current test for cancelling a pesticide, it would seem that if the Administrator can make this determination he or she should cancel the pesticide rather than merely making the identify of the inert ingredient available to the public.

Section 10(g). Data release restrictions on multinationals eliminated.

In 1978 Congress ordered release of pesticide safety testing data to the public, but ordered that such data not be "delivered" to agents or employees of multinational pesticide producers. This latter restriction justifies significant controls on the public's access to and use of the data. Locked rooms, affidavits, copying and publication restrictions, are all justifiably imposed to prevent the safety studies from reaching multinationals. This bill deletes this restriction as burdensome and unnecessary. The pesticide companies have never demonstrated that any economic harm occurs or would occur from the release of animal safety studies to competitors, foreign or domestic. The patent act and treaties provide basic product innovation protection. The 1978 multinational limitation was imposed on the theory that such studies have value to competitors in non-patent-treaty nations. Yet, no such nation has been identified as requiring such studies as a pre-licensing condition in that country. Absent such a showing, the safety studies have virtually no economic value to competitors, but are a significant source of harrassment to the public, especially these without legal counsel to fight industry claims under this provision.

Section 11. Private record keeping requirements permitted.

Current law prohibits the administrator from requiring private applicators to keep pesticide spray records. Such records are critical to establishing causation in both acute and chronic poisoning cases. They are also fundamental for public and worker health investigations and epidemiological studies. In reality, most growers do keep some spray records so that they can evaluate their spraying program cost and effectiveness. The Administrator should have the authority to require that such records to be kept and made available for inspection. This amendment would require the Administrator to promulgate such regulations.

Section 15. Repeal Indemnification Provisions for Suspensions and Emergency Orders.

Section 15 requires EPA to compensate pesticide companies, wholesalers and retailers for losses incurred when EPA issues a suspension order or an emergency order to prevent an imminent hazard. This provision acts as a significant disincentive to recall existing stocks of suspended pesticides and to issue emergency orders even when the agency takes the position that the pesticide presents an imminent hazard. The agency should not be required to compensate those economically damaged by an action taken to protect the public from an imminent hazard. If economic harm occurs, the pesticide companies, who have profited from the sale of the pesticide, should absorb the losses.

Section 16. Private Right of Action.

FIFRA should be amended to include a private right to sue for violations of the Act.

First, in regard to enforcing FIFRA and State pesticide laws, the states and EPA have been extremely lax. The General Accounting Office Report, Stronger Enforcement Needed Against Misuse of Pesticides (Oct. 1981), documents this problem.

Second, the EPA 1984 budget request seriously limits both the agency's and the states' manpower and financial capability to enforce pesticide laws.

The private right to sue does not require citizens to beg EPA or their state governments to help them. It allows a victim to bring suit against FIFRA violators. In an era of declining government regulatory enforcement, it is only fair to give the private citizen the right to protect him or herself.

Third, the injury rate for pesticides has been increasing as the rate of pesticide usage increases. The EPA Pesticide Incident Monitoring System has received over 55,000 pesticide injury incident reports over the past several years. These reports show an increase in incidents over the years. Meanwhile, pesticide production in this country has increased from 200,000 pounds in 1950 to over 1.7 billion pounds in 1980. As long as this trend continues there is little doubt that more and more Americans will suffer pesticide-related injuries. Medical doctors and scientists fear that many pesticides, in addition to causing acute short-term injuries to workers and other victims, may cause even more serious long-term injuries such as birth and genetic defects and cancer. Some means must be found to stop involuntary pesticide poisoning. Providing citizens a private right to sue is one small step in the right direction.

Fourth, simple justice demands that this amendment be passed. The proposed draft tracks the language of the Water Pollution Control Act, 33 U.S.C. §1365 with these exceptions: it explicitly allows aggrieved parties to seek damages as well as equitable relief; it specifies FIFRA violations which are actionable; and it waives notice requirements to the government or alleged violators where there is an imminent hazard to humans or the environment.

Many other environmental statutes permit citizen suits including the Safe Drinking Water Act, 42 U.S.C. §300, the Clean Air Act, 42 U.S.C. §1857, the Noise Control Act of 1972, 42 U.S.C. §4911, and the Marine Protection, Research and Sanctuaries Act of 1972, 33 U.S. §1415.

One environmental law authority, analyzed the public policy rationales underlying recently enacted environmental citizen suit provisions: "While Congress by no means has discarded the notion of public control of public persecutions, the routine fashioning of citizen suit provisions recognizes that compliance with environmental laws is the business of an alert community as well as of trained specialists. Several hypotheses justify citizen enforcement: it is less costly; the private enforcer is in a better position to weigh costs and benefits of a particular initiative; total resources devoted to enforcement are augmented; and competition from the private sector sharpens the response of public officials." W. H. RODGERS, ENVIRONMENTAL LAW (1977).

The U.S. House of Representatives in H.R. 5203, approved a private right to sue for FIFRA violations during the last session of Congress.

Section 17. Requiring that Foreign Governments Receive All Notices of Pesticide Cancellations.

Consistent with other amendments equating voluntary cancellations with "for cause" cancellations, this amendment would require that foreign governments be notified of voluntary cancellations of exported products.

Section 18. Tightening and Eliminating Emergency Exemption Loopholes.

The proposed amendments to Section 18 are designed to provide a legislative remedy to the well-documented and widespread abuse of this provision by EPA. As noted in the Benbrook report (p. 35) Sections 18 and 24c provide registrants an opportunity to circumvent the exclusive use and data compensation provisions of Section 3. In 1978, 165 Section 18 exemptions were granted. In 1982, 727 were granted, representing a 4.4 fold increase.

Proponents of the re-registration of Compound 1080 are using the Emergency Exemption section in an effort to use the chemical before a Section 3 registration is granted. At least four states (Wyoming, Montana, South Dakota, and Idaho) and possibly a fifth (Utah) have filed requests for emergency exemptions. Attempts to use the emergency exemption requirement to allow use of ferriamicide (mirex) to kill fire ants were halted by a federal district court in the fall of 1982.

The amendments specify criteria that the Administrator must use in granting emergency exemptions and provide for notice and public comment. Finally, the Administrator's decision must be supported by the public record.

Section 21. Solicitation of Advice.

Section 21 currently allows the Administrator to seek the views of all interested persons in connection with suspension, cancellation and other actions. The new amendment would make this mandatory. The intent is to prevent exclusive consultation with the pesticide industry.

Section 22. Transfer of Farmworker Jurisdiction to OSHA.

The OSHAct is a superior worker protection statute than FIFRA. OSHA enforces the Act more effectively than EPA enforces FIFRA.

The OSHAct has as its primary mission the protection of our nation's working people. The OSHA administration which administers OSHA has developed expertise in the area of occupational safety and health.

The Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §136 et. seq. by comparison, is a regulatory statute; occupational health is not its primary or even secondary concern. The EPA, which administers FIFRA, lacks expertise in the area of occupational safety and health.

The OSHAct standards concerning toxic substances require "the attainment of the highest degree of health and safety protection for the employee" 29 U.S.C. §655(b)(5). The Supreme Court has interpreted this provision to "require the elimination, as far as feasible, of significant risks of harm." I.U.D., AFL-CIO v. Ameri. Petr. Inst. 48 U.S.L.W. 5022, 5031 (July 2, 1980). In comparison FIFRA's weak standard provides much less protection for workers. It is a classic pro-industry law and requires a cost-benefit analysis of a product's "unreasonable risk(s) to man or the environment, taking into account the economic, social, and environmental cost-benefit of the use of any pesticide."

OSHA requires employer measurement of exact exposure levels of toxic substances while EPA only regulates 12 pesticides for reentry time periods of 24-28 hours. Employers are not required under FIFRA to measure exposure levels at all.

OSHA requires many other things which FIFRA does not require such as detailed medical surveillance, employee information and training, respirators and replacement of protective clothing and safeguards against employer retaliations.

Besides standard-setting OSHA is superior to EPA concerning enforcement: OSHA can enforce its standards directly; EPA may enforce only indirectly for failure to comply with label instructions. OSHA has a detailed inspection, complaint, and enforcement system while EPA's sytem is miniscule. OSHA enforcement, although almost eliminated by this Administration, is still more effective than EPA's.

The OMICA Case -- Farmworkers were unsuccessful in trying to force OSHA in 1975 to promulgate permanent enforceable farmworker pesticide standards in Organized Migrants in Community Action v. Brennan, 520 F.2d 1161 (D.C. Cir. 1975).

Judge Tamm, in OMICA, perhaps anticipating EPA's failure to protect farmworkers from pesticide hazards, stated:

> If in the future the enforcement provisions of FEPCA are found to be inadequate, we are confident that Congress stands ready to rectify the situation. However, the decisions to be made are legislative rather than judicial and properly remain the Congress province.

There is no rational reason why farmworkers, unlike all other American workers, are denied OSHA protection against these toxic chemical dangers.

For all the foregoing reasons it is essential to amend FIFRA to transfer pesticide protection for agricultural workers from the EPA to OSHA.

Section 24(b). State Required Labelling.

The current Act prohibits the states from requiring labelling or packaging different from the federal requirements. The new amendment would provide an exception for uses that a state prohibits. The amendments would require that the label or packaging shall state that uses are prohibited in the state where they are prohibited. This is simply a matter of informing consumers of unlawful uses of a pesticide product so that they do not innocently violate the law.

Section 24(c). Special local needs registrations limited to special local needs.

A recent report to the House agriculture operations subcommittee demonstrates that pesticide companies have widely abused the special local needs registration program to market pesticides throughout the country, state by state, as special local needs. This end-run enables them to avoid meeting the federal testing requirements under Section 3(c). This bill requires strict agency scrutiny of 24(c) registrations, and requires veto of such registrations where they are not special and local. It creates a negative rebuttable presumption that is triggered when five or more state registrations have been obtained. These registrations will expire automatically after five years and may be reissued by the state.

Section 24(c). Mandatory Suspension of Special Local Needs Authority for States that Fail to Exercise Adequate Controls.

The statute currently provides that the Administrator "may" suspend state authority if it fails to exercise adequate controls. The amendment would require the Administrator to do so.

Section 25(d). Protecting Persons Living in and Around Pesticide Treated Areas.

FIFRA should be amended to require the EPA Administrator to issue regulations governing critical areas of pesticide use.

Pesticide injury to members of the public living and working near treated areas is a serious and widespread problem in the United States today.

Rather than even attempting to establish minimum standards through regulation, EPA relies almost exclusively on labels to set standards for pesticide use. The labels are a potentially valuable tool, but they do not and cannot address all of the critical areas of pesticide use which are necessary to protect the public. Moreover, labels ordinarily are directed towards users, not the general public.

Both EPA and State officials (under amendments proposed here) will be better able to effectively prosecute misuse violations if they are armed with specific enforceable regulations.

As already mentioned, common law tort remedies have been inadequate to help pesticide poisoning victims deter FIFRA violations. See SUPERFUND STUDY GROUP, [97th CONG., 20 SESS.] INJURIES AND DAMAGES FROM HAZARDOUS WASTES -- ANALYSIS AND IMPROVEMENT OF LEGAL REMEDIES (Comm. Print 1982).

While there may be substantial conflict over the specific content of particular regulations, it is clear that the subject areas and general requirements are reasonable. Since the Administrative Procedure Act governs the adoption of regulations by the Administrator, all parties are assured ample opportunity for expressing their views before the specific regulations are adopted.

Section 25(e). Scientific Advisory Panel.

The current bill also provides for an advisory panel to advise and comment on Administrative actions. The amendments make certain that the members of this panel are chosen from a wide variety of disciplines and provide for a staggered three-year term of office for each member.

Section 26(a). Requiring States to Enact Enforcement Laws as Stringent as Federal Law Prior to Receiving Primary Enforcement Authority.

Congress should amend FIFRA Section 26 to require that before EPA grants a state primacy, that state should pass laws which are at least equivalent to or more stringent than FIFRA. The Occupational Safety and Health Act and many other federal statutes grant a state the right to enforce its own laws if its state plan is equal to or more stringent than the federal law. There is no good reason why FIFRA should be any less protective.

Congress intended for the EPA and the states to protect "man and the environment" by enforcing the pesticide laws under

FIFRA, Section 26. Under that provision states may obtain primary enforcement authority if the EPA Administrator finds that the state has adopted "adequate" pesticide use laws, has adopted adequate procedures for implementing those laws and has kept certain records required by the Administrator.

Unfortunately, there has not been even minimally effective enforcement of these laws. (See Government Accounting Office Report, Stronger Enforcement Needed Against Misuse of Pesticides (Oct., 1981). Therefore, the intent of Congress to protect man and the environment from pesticide misuse has not been accomplished for the reasons set forth below.

States are not required under Section 26 to have misuse laws equal to FIFRA. None, except perhaps for California, are equal. All Section 26 requires is that states have "adequate" laws. Presently, no state, not even California, has laws which permit it to enjoin or fine persons who misuse pesticides under state agency administrative proceedings. States only have the power to refer misuse cases to county, district or state attorneys. County prosecutors rarely, if ever, have sued growers for misusing pesticides. First, in every state the misuse of pesticides is a misdemeanor, not a felony. County prosecutors don't give priority to suing local growers for misusing pesticides when they have murders, rapes, robberies and other serious felonies to prosecute. Second, proving pesticide violations are not easy. It generally takes as much work to prove pesticide misuse as it does to prove a major felony. Third, suing local growers for misusing pesticides requires a prosecutor with unusual courage and conviction to withstand intense local pressures.

Section 32. Registration Fees.

Amended Section 32 will make the registration process pay for itself. It is consistent with Congressional policy on charging full cost for pesticide tolerance reviews. 21 U.S.C. 346(c).

Section 33. Antiretaliation.

Section 33 of FIFRA would be added to make it an offense to discharge or adversely affect the employment status of any employee because he or she has exercised rights granted under the Act, filed complaints concerning violations of the Act, has testified concerning violation of the Act, or has participated in a proceeding under the Act. The need for such a section should be obvious in today's EPA. It is also necessary to protect scientists and other employees that work for pesticide companies in order to ensure their objectivity and cooperation with EPA.

TESTIMONY OF RALPH ENGEL
PRESIDENT
CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

MY NAME IS RALPH ENGEL, I AM PRESIDENT OF THE CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION (CSMA) LOCATED AT 1001 CONNECTICUT AVENUE, NW, WASHINGTON, D. C.

CSMA HAS A MEMBERSHIP OF NEARLY 400 FIRMS ENGAGED IN THE MANUFACTURE, FORMULATION, DISTRIBUTION, AND SALE OF INSECTICIDES; DISINFECTANTS AND SANITIZERS; DETERGENTS AND CLEANING COMPOUNDS; AUTOMOTIVE CHEMICALS; AND WAXES, POLISHES, AND FLOOR FINISHES FOR HOUSEHOLD, INSTITUTIONAL, AND INDUSTRIAL USES. A SIGNIFICANT NUMBER OF THESE PRODUCTS HAVE PESTICIDAL CLAIMS AND ARE, THEREFORE, SUBJECT TO EPA JURISDICTION PURSUANT TO THE REQUIREMENTS OF THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT (FIFRA) AS AMENDED.

SPECIFICALLY, CSMA REPRESENTS THE NONAGRICULTURAL PESTICIDE INDUSTRY, INCLUDING DISINFECTANTS AND SANITIZERS; HOME, LAWN AND GARDEN INSECTICIDES; AND A WIDE VARIETY OF OTHER INSECTICIDES FOR HOME, INDUSTRIAL AND INSTITUTIONAL USE.

WE AT CSMA WOULD RESPECTFULLY URGE THE SENATE SUBCOMMITTEE ON AGRICULTURE RESEARCH AND GENERAL LEGISLATION TO SUPPORT S. 1263 WITHOUT CHANGE OR MODIFICATION. WE FIRMLY BELIEVE THAT A SIMPLE TWO-YEAR REAUTHORIZATION IS NEEDED FOR FIFRA.

ALTHOUGH WE FULLY SUPPORT S. 1263 AND ITS TWO-YEAR REAUTHORIZATION, WE WOULD LIKE TO TAKE THIS OPPORTUNITY TO BRIEFLY DISCUSS SOME OF THE CONCERNS THAT WE HAVE WITH THE EXISTING STATUTE INCLUDING:

1) REGISTRATION DATA GUIDELINES; 2) THE DISTINCTION BETWEEN AGRICULTURAL AND NONAGRICULTURAL PESTICIDES; 3) USER FEES FOR PESTICIDE REGISTRATION; 4) POTENTIAL LABELING PROBLEMS; 5) USE OF INDUSTRY LABORATORIES FOR TESTING PURPOSES; 6) PESTICIDE REGULATION BY STATE POLITICAL SUBDIVISIONS UNDER SECTION 24(A); 7) STATE REGISTRATION DATA PROBLEMS UNDER SECTION 3; AND 8) EPA SHOULD MAINTAIN A BIOLOGICAL TESTING FACILITY AT BELTSVILLE, MARYLAND; AND 9) REAUTHORIZATION OF FIFRA WITH AN EXTENSION OF THE

Scientific Advisory Panel (SAP).

1) Development of FIFRA Registration Data Guidelines -- CSMA has in the past expressed serious concern over the development and implementation of guidelines which are intended by Congress to set forth the kinds of data which would be required to support a registration.

The congressional intent behind section 3(c)(2) of FIFRA is to specify generally the kinds of basic data or information which may be required to support a registration, but at the same time permit latitude and flexibility on the part of scientists in developing their data.

Despite that intent, what evolved prior to recent agency policy changes was a set of rigid test protocol requirements which removed virtually all scientific judgment and which were being enforced by EPA reviewers as regulations rather than as of guidelines.

During the 97th Congress, CSMA worked with EPA, members of Congress, and other interested parties to achieve some legislative changes to FIFRA, section 3, to correct the guidelines problems. Legislative language providing for publication of flexible guidelines and modifications in the Federal Register and for submission of public comment for agency guidance was adopted by the House when it passed H.R. 5203 on August 11, 1982. This language was also included in S. 2620 as approved by the Senate Committee on Agriculture, Nutrition and Forestry on September 15, 1982. Since no further action occurred on FIFRA during that session, this much needed guidelines language was not enacted.

We are pleased to report that EPA has made the testing protocol guidelines available through the National Technical Information Service. This portion of the guidelines will not be treated as regulations, and thus corresponds with the CSMA position. The actual data requirements (as opposed to test protocols) have been formally proposed as regulations (47 Fed. Reg. 53192, November 24, 1982), but do attempt to distinguish between agricultural and nonagricultural data requirements. CSMA submitted extensive comments to EPA on February 25, 1983.

While EPA has moved a long way in addressing this problem, we believe that the FIFRA statute should appropriately address this issue, so as to reflect congressional intent similar to that expressed in H.R. 5203 during the last Congress.

2) Distinction Between Agricultural and Nonagricultural Pesticides-- Congress added a new requirement to FIFRA in 1978 to the effect that regulations prescribed by the Administrator to carry out the Act must take into account the differences in environmental risk, and the appropriate data for evaluating such risk, between agricultural and nonagricultural pesticides. This amendment extended the provision in the existing law which required the Administrator to take into account the difference in concept and usage between various classes of pesticides, by mandating the Administrator to apply such distinction in prescribing and evaluating data for nonagricultural pesticides. (See FIFRA section 25(a)(1), 7 U.S.C. section 136w(a)(1).)

The House Report on these amendments recognizes the importance of the nonagricultural portion of the industry and directs the Agency to develop expertise among its scientific and regulatory staff with respect to the nonagricultural pesticide industry:

> Pesticides regulated under this Act include not only agricultural pesticide products but also disinfectants and sanitizers, home, lawn and garden insecticides, as well as a wide variety of other pesticides for home, industrial and institutional use. These nonagricultural pesticides encompass well over half of the current registrations under this Act. While the Act presently requires that the Administrator take into account differences in concept in uses between various classes of pesticides, this additional language emphasizes that the Subcommittee expects EPA to acquire expertise among its scientific and regu-

LATORY STAFF SO THAT REGISTRATION IN THIS
AREA RECEIVES APPROPRIATE ATTENTION.

H.R. No. 95-663, 95TH CONG., 1ST SESS., 47, (OCTOBER 5, 1978). THE CONFERENCE COMMITTEE ADOPTED THE HOUSE POSITION IN THIS REGARD. (S. REP. NO. 95-1188, SUPRA AT 42-43.)

THE AGENCY HAS NOT, IN FACT, YET FULLY IMPLEMENTED THIS CONGRESSIONAL DIRECTIVE. WE RESPECTFULLY URGE THIS SUBCOMMITTEE TO PROVIDE SPECIFIC LANGUAGE DIRECTING EPA TO SEPARATE OUT AND UTILIZE CURRENT ADMINISTRATIVE STAFF TO SPECIFICALLY ADMINISTER ANY REGULATIONS AND GUIDELINES WHICH PERTAIN TO THE NON-AGRICULTURAL PORTION OF THE PESTICIDE INDUSTRY.

3) USER FEES FOR PESTICIDE REGISTRATION--THE ADMINISTRATION IS PROMOTING THE ESTABLISHMENT OF USER FEES WHEREBY THE BENEFICIARIES OF GOVERNMENTAL PROGRAMS PAY FOR THESE SERVICES IN A DIRECT WAY.

A FEDERAL USER FEE FOR PESTICIDE REGISTRATIONS IS NOT DESIRABLE DUE TO ITS IMPACT ON DEVELOPMENT COSTS, PARTICULARLY FOR SMALL BUSINESSES, AND ITS EFFECT OF INHIBITING THE REGISTRATION OF NEW OR IMPROVED PRODUCTS.

A FEASIBILITY STUDY MANDATED BY PL 95-396 WAS PREPARED AND A REPORT DELIVERED TO CONGRESS. THE ESSENTIAL FINDINGS WERE THAT THE ESTABLISHMENT OF A FEE SCHEDULE FOR REGISTRATION ACTIONS WOULD BE TECHNICALLY AND ADMINISTRATIVELY FEASIBLE; HOWEVER, THE OFFICE OF PESTICIDE PROGRAMS (OPP) RECOMMENDED THAT GIVEN THE LARGE NUMBER OF COMPLEX ACTIVITIES TAKING PLACE IN IMPLEMENTING THE NEW AMENDMENTS IN PL 95-396, IT WAS NOT PRUDENT TO INSTITUTE A FEE SYSTEM AT THAT TIME. ONCE THE BULK OF THE 1978 AMENDMENTS WAS INTEGRATED IN TO OPP OPERATIONS, OPP WAS INSTRUCTED BY THE OFFICE OF MANAGEMENT AND BUDGET (OMB) TO AGAIN REVIEW THE ISSUE OF FEES FOR REGISTRATION. IN LATE AUGUST, 1982, OMB POSED THE ISSUE OF WHETHER FEES SHOULD BE ESTABLISHED.

ON SEPTEMBER 27, 1982, CSMA SUBMITTED A LETTER TO EPA OPPOSING THE IMPLEMENTATION OF A USER FEE AT THE AGENCY FOR PESTICIDE REGISTRATIONS. CSMA'S OBJECTIONS TO SUCH A PROCEDURE ARE SIXFOLD. FIRST, USER FEES WOULD BE UNFAIR BECAUSE EPA BENEFITS THE GENERAL PUBLIC, NOT JUST THOSE WHO PRODUCE PRODUCTS TO BE REGISTERED.

SECOND, IF USER FEES PAY FOR MOST OF THE AGENCY'S EXPENSES, THERE IS NO REAL COST CONSTRAINT ON THESE REGULATORY OPERATIONS. IN ADDITION, THERE ARE FEW CONGRESSIONAL INCENTIVES TO SCRUTIZINE THE EPA'S REGULATORY ACTIVITIES TO SEE IF THEY ARE NECESSARY OR COST-EFFECTIVE. THIRD, A SYSTEM OF PESTICIDE REGISTRATION FEES WOULD DRAMATICALLY INCREASE PRODUCT DEVELOPMENT COSTS AND HAVE AN UNFAIR AND DISPROPORTIONATE IMPACT ON SMALL BUSINESSES. FOURTH, IMPOSITION OF REGISTRATION FEES ON THE FEDERAL LEVEL WOULD ADD TO THE CONSIDERABLE NUMBER OF SIMILAR EXPENDITURES ALREADY REQUIRED AT THE STATE LEVEL. FIFTH, DUE TO THE PRECLEARANCE MARKETING PROCEDURES IN THE REGISTRATION PROCESS, IT WOULD BE INEQUITABLE TO CHARGE PESTICIDE PRODUCERS FOR THE COST OF A PROGRAM WHICH INHIBITS THEIR ABILITY TO MARKET THEIR PRODUCTS. SIXTH, A USER FEE HAS BEEN FREQUENTLY INTERPRETED TO BE A TAX OR A REVENUE-RAISING MEASURE, AND CONSEQUENTLY COULD GIVE RISE TO A JURISDICTIONAL CONCERN.

UNDER THE SUGGESTED ADMINISTRATION PROGRAM, FEES (RANGING FROM $700 TO $25,000) WOULD BE CHARGED ON: 1) NEW CHEMICAL REGISTRATIONS; 2) OLD CHEMICAL REGISTRATIONS; 3) NEW BIORATIONALS; 4) AMENDED REGISTRATIONS; AND 5) EXPERIMENTAL USE PERMIT PROCESSING. WHILE THE INDUSTRY WOULD HAVE TO PAY FEES AT BOTH THE STATE AND FEDERAL LEVEL, EXCLUSIONS WOULD BE CONSIDERED WHEN FOREIGN, STATE OR LOCAL GOVERNMENTS ARE INVOLVED (SUCH AS EMERGENCY EXEMPTIONS AND SPECIAL LOCAL NEED REGISTRATIONS) OR WHERE THE COST OF COLLECTING FEES WOULD BE A SIGNIFICANT PORTION OF THE FEES COLLECTED (SUCH AS SUPPLEMENTAL OR MINOR USE REGISTRATIONS).

ALTHOUGH NO DEFINITE DECISION HAS BEEN MADE AT EPA AND OMB, AT THIS TIME, WE BELIEVE SUCH A PROGRAM IS ILL-ADVISED AND WE THEREFORE URGE THE SUBCOMMITTEE TO REJECT IT SHOULD IT BE FORTHCOMING.

4) LABELING PROBLEM UNDER SECTION 24(B)--IN OUR LAST TESTIMONY BEFORE THIS SUBCOMMITTEE, WE CALLED YOUR ATTENTION TO INCONSISTENCIES IN LABELING REQUIREMENTS GENERALLY CAUSED BY PRODUCT MANAGERS RECOMMENDING OR REQUIRING A LABEL FORMAT CONTRARY OR IN ADDITION TO EXISTING LABELING REGULATIONS (40 CFR SECTION 162.10). WE NOTED ALSO THAT EPA'S LABEL IMPROVEMENT PROGRAM AND DRAFT LABELING

GUIDELINES (SUBPART H ENTITLED, "LABEL DEVELOPMENT AND IMPROVEMENT") WERE CAUSING CONFUSION IN THE INDUSTRY WHICH WAS ALREADY TRYING TO COMPLY WITH EXISTING LABELING REGULATIONS. WE URGED THEREFORE THAT EPA MAKE NECESSARY LABEL IMPROVEMENT CHANGES THROUGH RULE-MAKING PROCEDURES WITH NOTICE AND OPPORTUNITY TO COMMENT WITH FINAL REGULATIONS BEING REFLECTED IN AMENDMENTS TO 40 CFR SECTION 162.10. OUR POSITION WAS THEN, AS IT IS NOW, THAT LABELING CHANGES ARE PROPERLY THE SUBJECT OF REGULATION WITH ITS ATTENDANT PROTECTION OF NOTICE AND OPPORTUNITY FOR COMMENT.

WE ARE PLEASED TO ADVISE THAT THE AGENCY WILL BE INCORPORATING LABEL CHANGES IN AMENDMENTS TO SECTION 3 REGISTRATION REGULATIONS TO BE PROPOSED SOMETIME IN THE NEAR FUTURE. IT IS ALSO OUR UNDERSTANDING THAT SUBPART H OF THE GUIDELINES PERTAINING TO LABELING WILL BE INCORPORATED WHERE PERTINENT INTO THIS OVERALL PROPOSAL. WE BELIEVE SINCERELY THAT THIS IS THE PROPER AVENUE FOR ASSURING THAT ALL REGISTRANTS ARE TREATED EQUALLY WITH RESPECT TO LABELING REQUIREMENTS BECAUSE SUCH PROCEDURES WILL RESULT IN THE ELIMINATION OF INCONSISTENCIES FOR LABELING OF SIMILAR PRODUCTS WITHIN THE INDUSTRY.

IN A RELATED MATTER, WHILE WE BELIEVE WE HAVE SEEN SIGNIFICANT STRIDES MADE BY THE AGENCY, ON LABELING, WE NEVERTHELESS STILL FIND A FEW STATES INTRUDING INTO THIS AREA FROM TIME TO TIME. SECTION 24(B) OF FIFRA SPECIFICALLY PROHIBITS STATES FROM REQUIRING LABELING IN ADDITION TO OR DIFFERENT FROM THAT OF THE EPA. WHILE THUS FAR WE HAVE BEEN ABLE TO DISSUADE SUCH ACTIVITY, WE BELIEVE THAT ADDITIONAL SUPPORT FROM CONGRESS IS NEEDED TO REINFORCE CONGRESSIONAL INTENT OF STATE PREEMPTION TO AVOID CONFLICTING LABELING REQUIREMENTS IN THE VARIOUS STATES. THIS REINFORCEMENT CAN BE ACCOMPLISHED BY RESTATING THE PREEMPTION LANGUAGE OF SECTION 24(B) IN THE SUBCOMMITTEE REPORT.

5) USE OF INDUSTRY LABORATORIES FOR TESTING PURPOSES--SOME CRITICS OF INDUSTRY TESTING HAVE SUGGESTED THAT IN ADDITION TO ITS OWN REVIEW THE EPA SHOULD REQUIRE THAT INDEPENDENT OR GOVERNMENT LABORATORIES REVIEW ALL DATA SUBMITTED UNDER FIFRA. WE BELIEVE THIS SUGGESTION IS INAPPROPRIATE, AND WE RESPECTFULLY URGE THIS SUBCOMMITTEE TO REJECT THIS APPROACH.

Industry laboratories are among the very best in the world and have some of the best scientific facilities and most highly-acclaimed research scientists. The record indicates that industry has done an excellent job of testing and has established the highest quality of research.

A Food and Drug Administration study (1969-1970) of laboratories around the nation concluded that the highest quality of research was conducted in industry laboratories when compared to independent and university and government laboratories. This study documents the quality of industry laboratories and reinforces the credibility of industry testing. We are certainly willing to explore all avenues by which we might improve the testing procedures of industry laboratories, but we strongly oppose any change in the present system of review of data submitted under FIFRA.

FIFRA contains comprehensive authority to require the testing of existing chemicals and the EPA is exercising that authority effectively. Simultaneously, the United States chemical industry has continued to place a substantial emphasis on voluntary health and environmental testing. As a result, impressive progress is being made in achieving FIFRA's objective of establishing a sound data base on the health and environmental effects of existing chemicals.

6) State Political Subdivisions Under Section 24(a)--During the 97th Congress, the Senate Committee on Agriculture, Nutrition and Forestry worked long and hard over the proposed changes in Section 24(a) dealing with "state authority," and I want to tell you how much we at CSMA appreciated your concerns and efforts to amend this section. Needless to say, the discussions over Section 24(a) were frequently misunderstood or misconstrued.

Although several of these same problems with 24(a) still exist today, we would like now to focus on only one segment of 24(a) dealing with whether or not political subdivisions of a state, such as a county or township, should be able to exercise the same pesticide jurisdiction as a state.

During the 1980s, there have been attempts by various

POLITICAL SUBDIVISIONS OF STATES TO GET INVOLVED IN THE PROCESS OF REGULATING THE SALE OR USE OF PESTICIDES OR REQUESTING GENERATION OF DATA.

BEFORE THIS PROBLEM SPREADS TO OTHER STATES, AND THEIR POLITICAL SUBDIVISIONS, THE STATUTE MUST BE CLARIFIED TO SAY THAT "A STATE, BUT NOT POLITICAL SUBDIVISIONS THEREOF, MAY REGULATE SALE OR USE OF PESTICIDES OR REQUIRE GENERATION OF DATA." WHILE THERE IS LEGISLATIVE HISTORY INDICATING A CONGRESSIONAL INTENT IN THIS REGARD, THE STATUTE CONTAINS NO EXPRESS PROHIBITION.

IN 1982, SENATOR S. I. HAYAKAWA INTRODUCED S. 2621 TO CLARIFY THE POLITICAL SUBDIVISION QUESTION. THE BILL RETAINED PRESENT STATE AUTHORITY TO REGULATE SALE OR USE OF PESTICIDES AND SPECIFIED THAT SUCH AUTHORITY RESTS WITH STATES, BUT NOT WITH POLITICAL SUBDIVISIONS THEREOF. THIS PROVISION WAS CONSISTENT WITH THE LEGISLATIVE HISTORY OF THE 1972 AMENDMENTS:

> "* * * [I]T IS THE INTENT THAT SECTION 24, BY NOT PROVIDING ANY AUTHORITY TO POLITICAL SUBDIVISIONS AND OTHER LOCAL AUTHORITIES OF OR IN THE STATES, SHOULD BE UNDERSTOOD AS DEPRIVING SUCH LOCAL AUTHORITIES AND POLITICAL SUBDIVISIONS OF ANY AND ALL JURISDICTION AND AUTHORITY OVER PESTICIDES AND THE REGULATION OF PESTICIDES" (S. REP. NO. 92-8838 (PART II) 92ND CONG., 2D SESS. 47 1972) APPENDIX E (EMPHASIS ADDED).

THE LIMITATION ON SUBSTATE AUTHORITY TO REGULATE PESTICIDES WAS RECOGNIZED IN 1980 BY THE ATTORNEY GENERAL OF MASSACHUSETTS IN DISAPPROVING PROPOSED BY-LAWS OF THE TOWN OF WENDELL WHICH ATTEMPTED TO REGULATE PESTICIDES. IN DISAPPROVING THE BY-LAWS, HE CONCLUDED IN PART:

> "THE FEDERAL ENVIRONMENTAL PROTECTION AGENCY IN ADOPTING REGULATIONS IMPLEMENTING THE FEDERAL ACT COMMENTED ON THE STATE AGENCY ADMINSTERING THE STATE PLAN AS FOLLOWS: 'IT IS NOT THE INTENTION OF THE ACT OR THESE REGULATIONS TO AUTHORIZE POLITICAL SUBDIVISIONS BELOW THE STATE LEVEL TO

> further regulate pesticides. Federal Register, Vol. 40, No. 49, Wednesday, March 12, 1975, at page 11700. The comments pertained to 40 CFR 171.7(a).'"

Similarly, in New York, ordinances adopted by a municipality regulating pesticides have been held invalid on the grounds that either the federal law or state law, which were not in harmony with the regulations, preempted the field. Long Island Pest Control Association, Inc. et al v. The Town of Huntington, 341 N.Y.S. 2d 93 (1973). Affirmed, 351 N.Y.S. 2d 945 (1974).

Senator Hayakawa's provision regarding political subdivisions expressly incorporated this congressional mandate into the statutory language of FIFRA and thereby precluded the necessity for further adminstrative review or litigation. This clarification, however, in no way precluded cooperation between the industry and local governments.

On September 15, 1982, the Senate Committee on Agriculture, Nutrition and Forestry passed a compromise S. 2620 containing the Hayakawa language on 24(a) dealing with "a State, but not a political subdivision . . . ." Unfortunately, this provision died when the bill was not taken up on the Senate floor.

During the 97th Congress, there was considerable broad-based support for this change in section 24(a), including the support of the State of California. This problem exists today and threatens to spread to other political subdivisions having little if any understanding of the structure of the pesticide industry or ramifications of the attempted regulations. We believe that the statute ought to reflect the congressional intent that political subdivisions below the state level should not regulate the sale or use of pesticides.

7) State Registration Data Problems in Section 3 of FIFRA--In 1981 and 1982, CSMA actively pursued an amendment to section 24(a) of FIFRA and a number of issues were wrongly associated with this amendment, including "interference with state authority."
In fact, the term "24(a)" itself became a political "catch

PHRASE." TO REDUCE THE POLITICAL CHARGES ABOUT "STATES RIGHTS" AND STILL OBTAIN SOME RELIEF FROM THESE PROBLEMS, WE WOULD LIKE TO DISCUSS STATE REGISTRATION CONCERNS THAT MIGHT LEGISLATIVELY FIT WELL UNDER SECTION 3 OF FIFRA.

FIRST, A STATE MAY SEEK DATA FROM REGISTRANTS, BUT MAY NOT ITSELF HAVE A COMPENSATION PROGRAM THAT IS CAPABLE OF PROTECTING THE COMPENSABLE RIGHTS OF A COMPANY WHO SUBMITTED DATA TO EPA. UNDER SECTION 3(C), A COMPANY IS ENTITLED TO COMPENSATION IN THE EVENT THAT DATA IS RELIED UPON BY OTHER FIRMS IN OBTAINING THEIR OWN FEDERAL REGISTRATION. FOR EXAMPLE, A COMPANY MAY CITE ANOTHER FIRM'S DATA TO OBTAIN A FEDERAL REGISTRATION AND PROMISE TO COMPENSATE THAT FIRM FOR ITS RESEARCH AND DEVELOPMENT COSTS. AFTER OBTAINING THE FEDERAL REGISTRATION AT EPA, THE COMPANY SEEKS TO REGISTER THE SAME PRODUCT AT THE STATE LEVEL, AND DISCOVERS THAT IT CANNOT RECEIVE A STATE REGISTRATION BECAUSE IT CANNOT PHYSICALLY PRODUCE THE DATA THAT WAS CITED IN THE EPA FILES. UNDER THIS EXAMPLE, THE COMPANY THAT ORIGINATES THE DATA HAS REFUSED TO ALLOW ANOTHER FIRM TO CITE ITS DATA AT THE STATE LEVEL BECAUSE THERE IS NO STATE COMPENSATION PROGRAM. MANY FIRMS, ESPECIALLY SMALL COMPANIES AND "ME-TOO" MARKETERS, ARE EFFECTIVELY BEING LOCKED OUT OF THE STATE MARKET.

DURING THE 97TH CONGRESS, THE SENATE COMMITTEE CAREFULLY EXAMINED THIS PROBLEM AND ADOPTED THE HAYAKAWA LANGUAGE FOR SECTION 24(A)(2)(A) THAT WOULD HAVE RESOLVED THESE CONCERNS IN A NONCONTROVERSIAL MANNER. THIS LANGUAGE STATED:

> "(A) WITH RESPECT TO DATA PREVIOUSLY SUBMITTED IN SUPPORT OF A FEDERAL REGISTRATION, THE STATE MAY REQUEST THE APPLICANT TO SUBMIT SUCH DATA TO THE STATE FOR REVIEW, AND IF THE APPLICANT DOES NOT PROVIDE THE STATE SUCH DATA AS IS REQUESTED, THE ADMINISTRATOR SHALL MAKE THE DATA AVAILABLE TO THE STATE, SUBJECT TO THE PROVISIONS OF SECTION 10. AT THE OPTION OF THE STATE, THE DATA MAY BE OBTAINED FROM THE ADMINSTRATOR UNDER THE PROVISIONS OF SECTION 10 WITHOUT FIRST MAKING THE

request to the registrant."

This problem still exists today, and will continue to present obstacles to getting products registered at the state level.

Second, many states do not have provisions covering the disclosure of confidential, proprietary, or trade secret business information; there are no provisions in the existing statute to deal with this problem.

Confidential trade secret information submitted to the EPA, but later forwarded to a state or utilized to register a product at the state level may not be protected from disclosure or may be inadvertently disclosed by the state. Although federal trade secret materials are protected under section 10 of FIFRA, there needs to be similar protection at the state level. Individuals, organizations or companies should not be able to circumvent the trade secret provisions of Federal FIFRA by securing the same data at the state level.

Third, during the past few years, our industry has faced a difficult problem in securing timely registrations of pesticide products at the state level, particularly in the State of California. During the last few months, however, considerable progress has been achieved in pesticide registrations in California, and we are pleased to report that the crisis that once existed has dissipated significantly. Although this problem has been reduced, it is not gone, and has appeared in other states.

Virtually all states have annual re-registration programs, and many states have enacted time-limits for the processing of state pesticide registrations, such as sixty or ninety days. To the best of our knowledge, we know of no state that specifically exceeds a ninety day registration period.

We believe there ought to be a federal provision in FIFRA to encourage the states to expedite the registration of pesticide products, and establish time limits, not exceeding ninety days, by which a registration should be approved.

We also believe that there ought to be consideration given to different types of products for state registration:

- O PREVIOUSLY REGISTERED PRODUCTS OUGHT TO BE EXPEDITIOUSLY PROCESSED AND ROUTINELY RE-REGISTERED WITHIN NINETY DAYS;
- O PREVIOUSLY REGISTERED PRODUCTS, SUCH AS "ME-TOO" PRODUCTS, OUGHT TO BE ROUTINELY REGISTERED AT THE STATE LEVEL WITHIN NINETY DAYS;
- O PREVIOUSLY REGISTERED GENERAL USE OR NON-RESTRICTED USE CONSUMER PRODUCTS FOR THE HOME, LAWN AND GARDEN SHOULD BE ROUTINELY REGISTERED WITHIN NINETY DAYS;
- O NEW PRODUCTS OR NEW USES OF OLD PRODUCTS (ALREADY FEDERALLY REGISTERED) MAY NEED TO BE SCRUTINIZED MORE CLOSELY BY STATE REGISTRATION OFFICIALS, AND THEREFORE MAY NEED MORE THAN 90 DAYS TO BE PROCESSED;
- O RESTRICTED USE PRODUCTS OR PRODUCTS USED IN THE PRODUCTION OF COMMERCIAL FOOD, FEED OR FIBER CROPS (ALSO FEDERALLY REGISTERED) MAY ALSO NEED MORE TIME.

DIFFERENT PRODUCTS PRESENT DIFFERENT PROBLEMS OR CONCERNS AND NOT ALL PRODUCTS SHOULD BE TREATED IN THE SAME MANNER. GENERAL USE AND RESTRICTED USE PRODUCTS ARE VERY DIFFERENT AND SHOULD OBVIOUSLY BE REGISTERED UNDER DIFFERENT STANDARDS SO AS TO BEST PROTECT HUMAN HEALTH AND SAFETY AND THE ENVIRONMENT.

NONE OF THESE CHANGES WOULD IN ANY WAY EITHER PROHIBIT THE STATE FROM EXERCISING ITS RIGHTS UNDER SECTION 24(A) TO REGULATE SALE AND USE OF PESTICIDE PRODUCTS OR PREVENT THE STATE FROM IMPLEMENTING ITS PREROGATIVE TO BAN, TO SUSPEND, TO CANCEL, OR TO DENY A STATE REGISTRATION OF A PESTICIDE PRODUCT.

FOURTH, BETWEEN 1979 AND 1982, CSMA MEMBERS EXPERIENCED CONSIDERABLE DIFFICULTY WITH THE ARBITRARY IMPOSITION OF ADDITIONAL STATE DATA REQUIREMENTS ABOVE AND BEYOND THOSE PRESENTLY REQUIRED BY EPA. THIS STATE PROBLEM BECAME SO ACUTE AND BURDENSOME ON OUR INDUSTRY THAT IT WAS A PRINCIPAL REASON FOR OUR SUPPORT OF A

24(a) amendment to FIFRA in the 97th Congress.

We are pleased that the full Committee on Agriculture, Nutrition and Forestry supported that amendment. We also want to commend the Senators for your perserverence in dealing with this difficult and complex issue.

Although considerable attention has been focused on the California registration problem over the last three years, California is only one state among several that have been involved.

There is a very real concern that other states will move toward implementing similar procedures. A multiplicity of states implementing policies such as those that existed in the 1979-1982 period in California would exponentially increase the burdens on the industry. We have already seen initiatives in several states that would increase unnecessarily the regulatory burden upon individual registrants seeking state registrations.

By way of illustration, let us remind you of the variety of attempts that have been made in different states to modify and broaden pesticide authority in ways that would result in unreasonable, unnecessary, or duplicative regulatory burdens:

New York:	Has attempted to require environmental impact statements prior to registration.
Massachusetts:	Would require submission of duplicate EPA data or generation of additional data. Would permit political subdivisions of the state to regulate pesticides.
Maine:	Has attempted to require environmental impact statements prior to registration.
West Virginia:	Would require notification of adjacent land owners, including absentees, of pesticide application.
Oregon:	Would extend pesticide regulatory authority to substate levels of government.
New Jersey:	Consideration of a model ordinance which would permit cities, townships, etc., to require permits, posting of signs, noti-

FICATION OF ADJACENT PROPERTY OWNERS AND OTHER RESTRICTIONS PRIOR TO SPRAYING OF EVEN HOUSEHOLD AEROSOL PESTICIDE PRODUCTS.

MOST RECENTLY, THE FLORIDA LEGISLATURE IS CONSIDERING HOUSE BILL PCB 10-A WHICH WOULD REQUIRE THE REGISTRANT TO SUBMIT ANY ADDITIONAL DATA OR EVIDENCE REQUIRED BY THE STATE AS PART OF A NEW "SYSTEMATIC PROGRAM OF DATA COLLECTION."

THIS PROBLEM HAS IMPORTANT IMPLICATIONS FOR ALL MARKETERS WHO SELL CONSUMER PRODUCTS ON A REGIONAL OR NATIONAL BASIS. DUE TO ITS IMPACT ON INTERSTATE COMMERCE AND THE ANTI-COMPETITIVE CONSEQUENCES OF THESE INITIATIVES, WE URGE THE SUBCOMMITTEE TO RECOGNIZE THESE PROBLEMS AND SEEK A FEDERAL LEGISLATIVE SOLUTION TO THEM BEFORE THE FACT, NOT AFTER.

8) EPA SHOULD MAINTAIN A BIOLOGICAL TESTING FACILITY AT BELTSVILLE, MARYLAND--SENATOR PAUL SARBANES (D, MD) HAS INTRODUCED S. 780, A BILL TO REQUIRE THAT THE EPA MAINTAIN A FACILITY FOR THE BIOLOGICAL TESTING OF PESTICIDES UNDER FIFRA.

WE BELIEVE IT IS APPROPRIATE TO HAVE ONE FEDERAL LABORATORY FACILITY THAT HAS THE AUTHORITY TO PROVIDE TESTING OF DISINFECTANT MATERIALS AND THUS AVOID CONFLICTS OVER TESTING METHODS AND TEST RESULTS.

WITHOUT SUCH A LABORATORY WE FORESEE THE POSSIBILITY OF FIVE, TWENTY OR EVEN FIFTY STATES OBTAINING VARYING TEST RESULTS ON THE SAME PRODUCT AND THEREBY TAKING DIFFERENT ENFORCEMENT ACTIONS. EVEN WITH ONLY THREE STATES CURRENTLY CONDUCTING THE TESTS, NAMELY FLORIDA, NORTH CAROLINA AND VIRGINIA, THERE IS EARLY EVIDENCE OF DIFFERING TEST RESULTS BETWEEN THEM. INSTANCES WHERE ONE STATE WOULD FAIL A PRODUCT AGAINST A TEST ORGANISM WHILE ANOTHER STATE WOULD OBTAIN PASSING RESULTS.

MULTIPLY THAT EXAMPLE BY HUNDREDS OF PRODUCTS AND YOU CAN SEE THE POTENTIAL CONFUSION THAT WOULD RESULT. NOW IF WE EXTEND THAT SCENARIO TO A POINT WHERE AN ENFORCEMENT ACTION IN ONE STATE IS BEING CHALLENGED, WE CAN ENVISION CONTRADICTORY DATA FROM OTHER STATE TESTING LABS BEING PRESENTED IN OPPOSITION TO THE DATA FROM THAT ONE STATE. THE CONFUSION THAT WOULD RESULT WOULD NOT BE APPEALING FOR

GOVERNMENT OR INDUSTRY. AND CERTAINLY THE CITIZENRY WOULD NOT BE WELL SERVED.

9) REAUTHORIZATION--SINCE ITS INCEPTION, THE HOUSE AND SENATE COMMITTEES DEALING WITH AGRICULTURAL MATTERS HAVE EXERCISED THEIR LEGISLATIVE JURISDICTION OVER FIFRA, AND WE HOPE THIS LEGISLATIVE LEGACY IS CONTINUED.

FIFRA, HOWEVER, WAS NOT REAUTHORIZED IN EITHER 1981 OR 1982 BY THE CONGRESS. THE PASSAGE OF A CONTINUING RESOLUTION KEPT THE PESTICIDE REGISTRATION PROGRAM AT EPA PROPERLY FUNDED. WE WOULD RESPECTFULLY URGE THIS SUBCOMMITTEE TO REAUTHORIZE FIFRA FOR TWO YEARS, AND THUS REFUTE ANY POSSIBLE JURISDICTIONAL CLAIMS MADE BY OTHER COMMITTEES.

IN ADDITION, THE SCIENTIFIC ADVISORY PANEL (SAP) HAD A SUNSET DEADLINE OF SEPTEMBER 30, 1981, AND HAS RUN OUT OF LEGISLATIVE AUTHORITY. IT ALSO NEEDS TO BE REAUTHORIZED SO THAT PROPER SCIENTIFIC PEER REVIEW CAN AGAIN BE UTILIZED TO COMMENT ON PESTICIDE MATTERS.

CONSEQUENTLY, WE WOULD RESPECTFULLY URGE THAT THIS SUBCOMMITTEE CONSIDER AT THIS TIME ONLY A SIMPLE REAUTHORIZATION FOR TWO YEARS, WITH A NEW SAP. WE FULLY SUPORT S. 1263.

WE BELIEVE IT WOULD BE MOST APPROPRIATE FOR THE NEW EPA ADMINISTRATOR TO HAVE SUFFICIENT TIME TO REVIEW THE AGENCY'S PRIORITIES AND TO REVIEW FIFRA AND THE PESTICIDE PROGRAMS.

ALTHOUGH WE HAVE COMMENTED ON SEVERAL PROBLEMS INHERENT IN THE EXISTING FIFRA STATUTE, WE SUGGEST THE SUBCOMMITTEE TAKE UP THESE MATTERS AT A FUTURE TIME, CERTAINLY AFTER THE SUPREME COURT HAS CONSIDERED THE CONSTITUTIONALITY OF THE EXISTING LAW UNDER THE MONSANTO CASE.

CONCLUSION--WE SHARE A COMMON CONCERN THAT ALL PESTICIDES, WHETHER USED NATIONALLY OR CENTERED LARGELY WITHIN A PARTICULAR STATE, ARE SAFE AND EFFECTIVE FOR THEIR INTENDED USES AND THAT THEY DO NOT POSE UNREASONABLE RISKS TO MAN AND HIS ENVIRONMENT. MANY OF THE CONCERNS WE HAVE DISCUSSED TODAY IMPOSE AN ECONOMIC BURDEN UPON OUR INDUSTRY AND DEPRIVE CONSUMERS OF SAFE AND EFFECTIVE PESTICIDES NEEDED TO CONTROL PESTS.

STATEMENT OF DENNIS BURCHETT, REPRESENTING PESTICIDE PRODUCERS ASSOCIATION

Our Association represents formulators, small manufacturers, importers and distributors engaged in the sale of pesticides to agriculture in the U.S. Our objective over the past few years in testifying before your Committee has been to seek changes in FIFRA needed for survival of some of our members and changes to remain competitive for others. We have had limited success in our efforts.

Members of PPA provide a direct link to the American farmer. In contrast to the larger national and international companies, our members generally serve local and regional markets. Our role in agriculture in the United States is maintaining fair competition in the market by producing innovative formulations and the formulating and distribution of products after patent expiration for the benefit of American agriculture and ultimately the American consumer.

The PPA supports the reauthorization of FIFRA as well as the reauthorization of the Scientific Advisory Panel. However, in view of the recent Monsanto Court decision which found certain sections of FIFRA to be unconstitutional, we suggest that this Congress should not make any substantial changes in the law until as such time the Supreme Court can rule on this lower court decision on constitutionality. We would, however, like to address some issues of specific concerns to our Association.

Gaining entrance into the market becomes more difficult each year with new regulations in FIFRA and the inevitable litigation that follows these regulations and amendments adding further restraints to the small producer. We are fully aware of and greatly appreciate the many hours your Committee and its staff have devoted to putting together S. 2620 in the last Congress in an effort to resolve some of the problems generated by FIFRA. Unfortunately, the old system is still in place. The problems facing our members today have not gone away and to our dismay have even worsened.

The Pesticide Producers Association has several major concerns involving changes in FIFRA. As a result of the recent Monsanto vs. EPA decision, certain sections of the law concerning the registration provisions of FIFRA - Section 3, were declared unconstitutional. This was a major set back for the small producer making it virtually impossible to obtain their own labels. There is little more that can be said at this point until EPA receives further clarification and the Supreme Court has heard this case and makes its decision. We can only say that major changes to section 3 are badly needed, but as already mentioned, we feel changes should not be made by Congress until after the Supreme Court decision.

Our membership has a problem with the present data call-in requirements of FIFRA under Section 3(c)(2)(b). Much work went into the text of S. 2620 in an effort to prevent one or two companies from locking out a smaller company possibly resulting in the smaller company losing its label. As you will remember the proposed language provided for market share and not equal share. We continue to feel a need for such a provision.

In view of the recent Ciba Geigy-NACA vs. EPA decision on cite-all we are still concerned as to how the EPA will permit data to be used. We feel it necessary that our member companies be permitted to produce their own data, cite specific data or a combination thereof. Although changes are currently proposed to address certain aspects of this issue, we are concerned those changes will not go far enough to fullfil our needs.

The complications of the data issue extend far beyond the federal level. There are also problems at the state level. Although not wide spread at this time, there are problems for the small formulator in obtaining certain state registrations. To compensate a data submitter in order to obtain a federal registration is one issue with built-in problems, but working out a similar system to obtain a state registration for a federally registered product just adds more tunnels to the maze that we must try to work through. If one is able to satisfy this requirement, the next problem is to be able to provide this data base (if it can be obtained) to the state. This too is not easily resolved as a data holder could be reluctant to give up data to a state in which confidentiality of data is not mandated by state law. This is another issue we feel deserves attention in the interest of small business.

There are continuing problems involving such issues as registration fees, new use, exclusive use periods and others. While these problems are not easily resolved, they most certainly will never be resolved without the help of Congress.

We continue to have concerns on Section 24. Although some problems still remain at the state level, an additional concern is the strong attempt by political subdivisions to impose further regulation. We feel the regulations already in place at the federal and state levels are more than adequate and the lowest political subdivision should be the state.

Mr. Chairman, our Association is fully aware of the magnitude of difficulty involved in resolving even those issues we have addressed let alone the variety of interests of others. It is our intent, however, to approach this Congress for sweeping major changes in FIFRA once the Supreme Court has handed down the decision on the constitutionality of this law. We are grateful for the opportunity of having presented our views and would be happy to answer any questions you or the other Committee members may have.

Thank you, Mr. Chairman.

Statement of

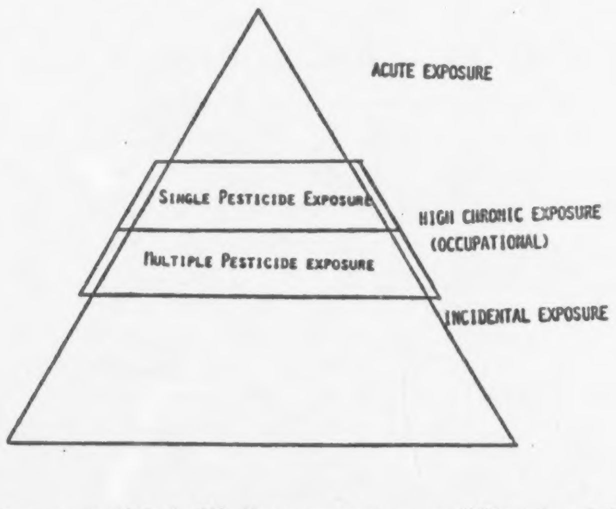
John E. Davies, M.D., M.P.H.

My name is John E. Davies, M.D., M.P.H., I am a physician and professor of the Department of Epidemiology and Public Health in the University of Miami School of Medicine, my curriculum vitae is attached to this statement.

I have been actively involved in medical aspects of human pesticide exposure for twenty years and have studied these in the United States and for the World Health Organization in many parts of the developing world. I am one of the original seven members of the FIFRA Scientific Advisory Panel and have served as the expert on epidemiology in this panel from December, 1976 to September, 1981. I feel therefore I am able to comment on the health concerns of pesticide exposure and EPA management of the pesticide program over the last decade from at least two different perspectives. To combine these two aforementioned perspectives, health effects and pesticide exposure, and the Agency's responses to these through its regulatory program, I will make no further comments on the benefits and enormous learning gains that I experienced while serving on the Science Advisory Panel, since this is the topic which the next speaker, Dr. Dwayne Torregeson will address in his presentation. Rather I would prefer to review the Agency's response to the pesticide program, insofar as health is concerned, in the terms of the health outcomes of the past, the present and the needs of the future.

Categorization of Exposure: [illegible] key to understanding the health effects of pesticide exposure is to categorize the exposure in terms of the amounts, types and durations of exposure sustained by man overtime and to study the disease end points associated with these different exposures. Current and past pesticide use patterns have resulted in three types of pesticide exposure categories shown in the figure.

CATEGORIES OF HUMAN PESTICIDE EXPOSURE



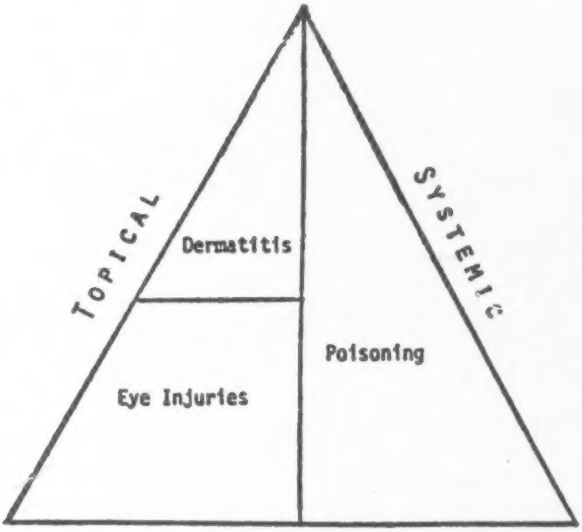
The diseases associated with these exposures are different and their recognition has evolved with time. Back over 10 years ago, pesticide poisonings were the main medical concerns. The clinical manifestations of acute exposures are shown in the figure below.

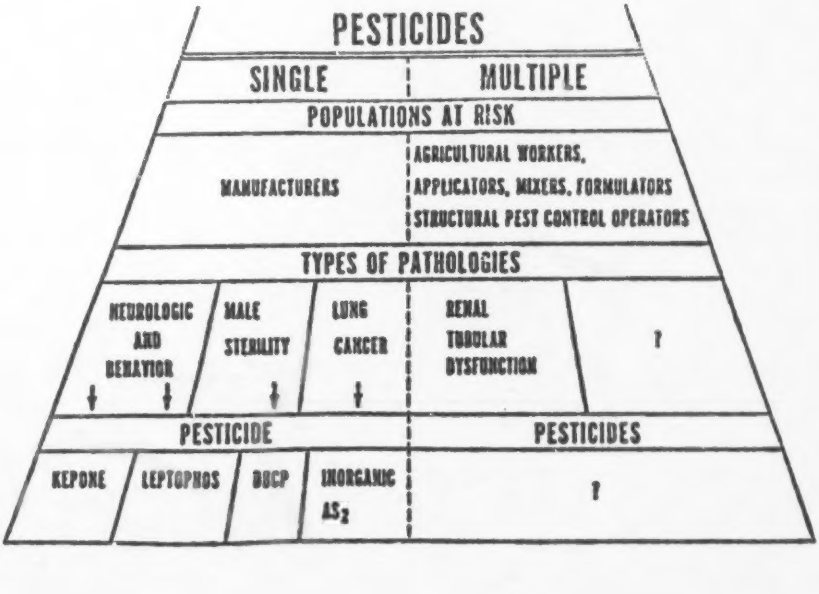
These were common, often fatal and a cause and effect relationship between exposure and poisoning obvious on a toxicological basis. Their magnitude was quantitated on the basis of mortality and hospital morbidity statistics.

Later on as a result of epidemiological studies and the occurrences of episodes of illness during manufacture of selected pesticides, health effects of chronic exposure became recognized.

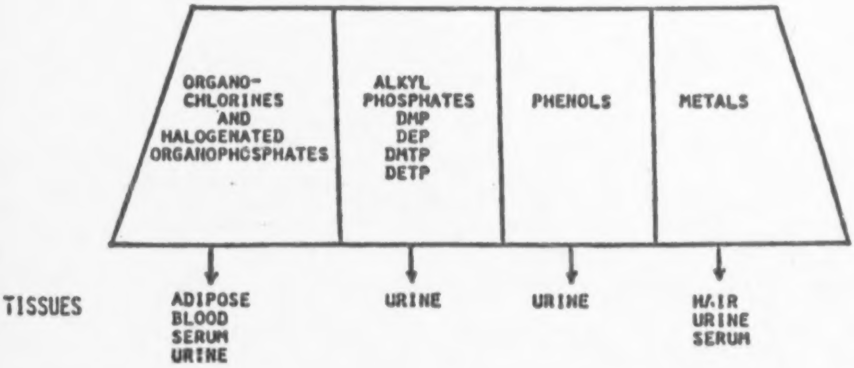
EPIDEMIOLOGY OF PESTICIDES

ACUTE EXPOSURES



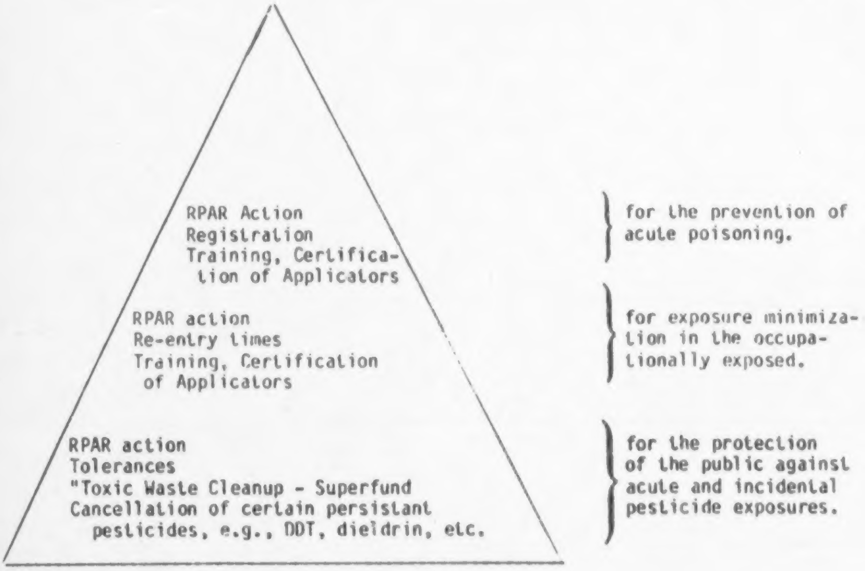


More recently, with the recognition of toxic waste dumps and localized areas of excessive incidental exposure, public health concern has risen for the adverse health effects of excessive incidental community exposures to multiple chemicals of varying degrees of toxicity. Many of the chemicals being identified in toxic waste sites are pesticides or contaminants of pesticides and some of these are very toxic.



Population Characteristics: Children, pickers, and mixers/applicators are population groups at greatest risk of acute pesticide poisonings. Migrant workers, pickers, mixers, applicators, and formulators are the occupational group sustaining chronic occupational exposure to pesticides. The general population sustains incidental exposure of trace amounts of pesticides in the air, water, and food of our modern environment.

The Environmental Protection Agency's Response: The EPA over ten years sought to control the real and potential adverse health and environmental effects of pesticides through 1) regulation, 2) research, 3) training, and 4) monitoring. The goal of all these endeavors has been to minimize or eliminate unwarranted pesticide exposure. Examples of types of regulatory action developed by the Agency, to the three different exposure categories include:


RPAR Action
Registration
Training, Certification of Applicators
for the prevention of acute poisoning.
RPAR action
Re-entry times
Training, Certification of Applicators
for exposure minimization in the occupationally exposed.
RPAR action
Tolerances
"Toxic Waste Cleanup - Superfund
Cancellation of certain persistant pesticides, e.g., DDT, dieldrin, etc.
for the protection of the public against acute and incidental pesticide exposures.

Outcomes: One method to measure the efficacy of regulatory action is to compare the health related problems of pesticides in countries where regulation and training are still in the formative phase, as is the case in many Third World countries. In the U.S., based on mortality statistics, the more serious pesticide problems are declining, but in other parts of the world pesticide poisonings have now become a major public health problem. For example, in Sri Lanka, 13,000 patients are hospitalized annually and 1,000 die. Another method of measuring the efficacy of regulatory action is obtained by measuring the health changes overtime. Secular changes of certain persistent pesticides in adipose tissues of the U.S. General Population is a case in point. The tables below show average adipose concentrations of DDT, Beta-BHC, and Dieldrin in blacks and whites in the U.S. from 1970-1978. Insofar as DDT is concerned, it will be noted that blacks are higher than whites and their concentrations have now declined to those levels which were seen in whites when DDT was cancelled in 1972. Presently, I am told specimens are collected, but remain unanalyzed because of budgetary constraint These data are striking testimonies to the regulatory and monitoring activities of the Agency. And, in my opinion, should emphasize the vital need for future support for these pesticide monitoring activities, particularly since there were 43 isolates of pesticides in the 425 toxic dumps which were listed by the Agency as being Superfund priority sites.

Future: As for the future, my experiences on the Science Advisory Panel lead me to conclude that the Agency has done a creditable job with regards to its regulatory responsibilities for pesticide exposure minimization, and protection of man in the environment. While I am supportive of the need for the adherence of the guidelines for registration of new pesticides and the need for RPAR activities when appropriate health risks are triggered by new data, I believe that the future needs of the Agency should be reordered with greater emphasis on the need for the cleanup of pesticides in the toxic waste dumps, and the need for stepped up monitoring of pesticides in man and his environment.

The achievement of these goals, I believe, will only be possible with increased support and interdisciplinary approaches to the pesticide problem involving agriculture, industry and the public sector, so that there can be a meaningful and equitable input of research and monitoring for each of these parties with the Environmental Protection Agency.

TEMPORAL CHANGES OF GEOMETRIC MEANS OF RESIDUES IN ADIPOSE TISSUE SELECTED ORGANOCHLORINE PESTICIDES IN THE U.S. WHITE POPULATION DURING THE PERIOD OF 1970-1978*

Geometric ± (ppm)

Year	N	Total DDT	Beta-BHC	Dieldrin
1970	1,373	7.46	0.44	0.22
1971	1,545	7.04	0.37	0.24
1972	1,877	6.23	0.30	0.21
1973	1,085	5.70	0.32	0.21
1974	892	4.96	0.23	0.18
1975	771	4.67	0.24	0.16
1976	667	4.38	0.25	0.14
1977	775	3.35	0.20	0.12
1978	802	3.64	0.19	0.12

*Personal Communication. Dr. Frederick W. Kutz, U.S. Human Adipose Tissue Monitoring Program.

TEMPORAL CHANGES OF GEOMETRIC MEANS OF RESIDUES IN ADIPOSE TISSUE SELECTED ORGANOCHLORINE PESTICIDES IN THE U.S. BLACK POPULATION DURING THE PERIOD OF 1970-1978*

Geometric ± (ppm)

Year	N	Total DDT	Beta-BHC	Dieldrin
1970	1,373	12.97	0.69	0.35
1971	1,545	16.21	0.65	0.35
1972	1,877	12.16	0.47	0.27
1973	1,085	9.66	0.37	0.27
1974	892	8.44	0.31	0.19
1975	771	7.04	0.27	0.16
1976	667	6.70	0.30	0.16
1977	775	4.47	0.19	0.11
1978	802	6.07	0.23	0.14

*Personal Communication. Dr. Frederick W. Kutz, U.S. Human Adipose Tissue Monitoring Program.

STATEMENT OF DEWAYNE C. TORGESON, Ph. D.

My name is Dewayne C. Torgeson. I have been employed by Boyce Thompson Institute for Plant Research, presently located at Cornell University, Ithaca, New York, since 1952, following receiving a Ph.D. degree in Plant Pathology from Oregon State University. I am currently Program Director of Bioregulant Chemicals and also serve as Corporate Secretary and Acting Treasurer. My scientific career at the Institute has been concerned with agricultural chemicals.

From December, 1976 to September, 1981, I served as a member and chairman of the FIFRA Scientific Advisory Panel. As you know, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel was a statutory committee, created on November 28, 1975, pursuant to Section 25(d) of FIFRA, as amended by Public Laws 94-140 and 95-396. A Charter was authorized for the Panel and renewed as reauthorization for the Panel was obtained. The authorization for the Panel terminated September 30, 1981.

I and other former Panel members are presently serving as consultants to the Office of Pesticide Programs in EPA and have assisted the Agency with peer review of certain risk assessments needed for regulatory decisions.

The primary congressional mandate to the Panel was to comment as to the impact on health and the environment of action proposed in notices of intent issued under section 6(b) (cancellations and changes in classification) and section 25(a) (proposed and final regulations) within the same time periods as provided for the comments of the Secretary of Agriculture under such sections.

The members of the Scientific Advisory Panel worked very diligently and responded in a thorough and expeditious manner to requests from EPA for the review of pending actions. During the six years of my Chairmanship, the Panel held a total of 52 meetings of from one to three days in length. The Panel's Executive Secretary and his staff were extremely helpful and untiring in providing support for the Panel.

At this point I would like to give you a feel for the activities of the Panel during 1979, - a typical year. The Panel held eleven public meetings during 1979. As authorized by the Act, the Panel reviews and comments on all regulations and other major regulatory actions authorized under Section 25(a) and 6(b). During 1979 the Panel considered a variety of draft, proposed and final regulations. The following is a compilation of major review actions: InterimFinal regulations for the conditional registration of pesticides; Notices for Concluding the Rebuttable Presumptions Against Registrations (PRARs) on Amitraz, Pronamide, DBCP, Trifluralin, Benomyl, Thiophanate-methyl, and Dimethoate; Notice of Intent to hold a hearing under FIFRA Section 6(b)(2) for regulatory action to conclude the RPAR on 2,4,5-T and silvex; Classification of Pesticides as Restricted Pesticides (two review actions involving classification of certain uses of 34 active ingredients as restricted pesticides); Proposed Guidelines for Registering Pesticides in the United States (Subparts F, Hazard Evaluation: Humans and Domestic Animals; G, Product Performance; I, Experimental Use Permits; and J, Hazard Evaluation: Nontarget Plants); Proposed regulations for Registration of Pesticides by States to Meet Special Local Needs; Recommended Tests for Potential DNA, Gene, and Spindle Effects from Use of Trifluralin; and a Preliminary Review of Draft Proposed Rulemaking for Subpart D, Chemistry Requirements - Product Chemistry of the Guidelines for Registering Pesticides in the United States.

Other activities of the Panel during the year included close liaison with the Science Advisory Board; administrative waivers on non-scientific matters; and participation on special studies. As Chairman of the Panel I served on the Executive Committee of the Science Advisory Board and provided close liaison on all activities of mutual interest to both Advisory Committees. During 1979, two members of the Scientific Advisory Panel served as ex-officio members of the Scientific Advisory Board to coordinate on a special study of tolerances on pesticides. Overall, the comments and recommendations of the Panel have made, in my opinion, a significant contribution to regulatory actions by EPA on pesticides.

The Panel always sought to be completely objective and spent many long hours studying means of documentation. The Chairman and members of the Panel were extremely careful to ensure that time was allowed for discussion on all aspects of topics under review. Some attendees at Panel meetings commented that Panel meetings were a refreshing change from other meetings because of open discussions and a genuine feeling that Panel members were guided by scientific concerns.

I believe the Panel has lived up to its charge by Congress. Indeed, the Panel has worked as an instrument whereby the rest of the scientific community could have input on matters which might affect the health and environment of this country. Since the Panel was mandated by Congress, members of the Panel considered themselves to be an extension of Congress. I believe the record of the Panel clearly reflects objective scientific thinking by a group of scientists who were uniquely qualified to provide expert advice on problems of health and the environment. The Panel operated independently of EPA, industry and environmental groups in reaching decisions on regulatory actions. The Panel was well balanced in terms of scientific disciplines enabling them to have a broad range of expertise. All meetings of the Panel were open to the public and were announced in the Federal Register 15 days before the meeting.

The Panel reviewed actions on cancellations or changes in classification; proposed and final regulations; Rebuttable Presumption Against Registration (RPAR) and provided advisory opinions to the Agency on such topics as aldicarb and permethrin. The Panel also worked with the Agency, industry and environmental groups in drafting up a set of registration guidelines for registering pesticides. This involved many drafts, meetings and several years of work by the Panel to accomplish the final publication by NTIS.

The Panel advised the Agency on the kinds of tests or studies to be done to gather the information needed to make valid judgements. The Panel repeatedly requested EPA to obtain monitoring data for the basis of good scientific decisions. The Panel assisted the Agency with a scientific review of issues of concern to public health. Topics included child resistant packaging, reentry protection for workers, restricted use pesticides, the pesticide monitoring plan, data requirements for 2,4-D, Agency scientific findings on carbaryl. There are many other actions which I could mention but will not take your time to go on.

Very importantly, the Agency responded to recommendations made by the Panel and more frequently than not accepted the Panel's recommendations. When recommendations were not accepted the Agency documented its rational for non-acceptance.

To conclude my remarks, I believe that the Panel has given a high degree of dedication in faithful and arduous labors since its inception and that it has, in fact, served the purpose for which it was created by Congress.

STATEMENT OF JAMES B. GRANT, EXECUTIVE SECRETARY, THE NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE

Mr. Chairman and members of the Subcommittee:

I am James B. Grant, Executive Secretary of National Association of State Departments of Agriculture. The Association consists of the chief administrators of state agriculture agencies. These agencies are responsible for the implementation of state laws pertaining to the sale and use of pesticides. State departments of agriculture also have responsibility under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) for enforcement activities, special local need registrations, filing for emergency exemptions and applicator training and certification.

Basic State responsibilities under FIFRA sections 18, 24, 26 and 27 date back to the landmark FIFRA Amendments of 1972. Since then, the States and EPA have made a great deal of progress in developing a strong partnership in pesticide regulations. Effective cooperation between state and federal regulators has helped assure the health and safety of the general public, while meeting the essential needs of pesticide users.

The Association appreciates the important responsibilities that Congress has entrusted to the States in regulating the sale and use of pesticides, and we believe that the States have exercised that authority in a highly responsible manner. Consequently, the Association remains firm in its determination to retain and defend the powers and responsibilities which Congress has entrusted to us under FIFRA, and which we have exercised in a prudent and responsible manner.

The Association believes that for the most part, pesticide regulatory problems can be dealt with administratively and within the framework of existing law. Nevertheless, we would like to call your attention to two relatively minor problem areas in some states where a change in the statute would help to expedite the regulatory process and strengthen State-EPA relations.

The first of these involves Section 27(a) which requires a State to "commence an appropriate enforcement action within thirty days of the referral of any pesticide use complaint by EPA." EPA has insisted that "enforcement action" means an action beyond the investigation stage, including a warning letter, scheduled hearing, or other appropriate presecutorial action. This interpretation causes difficulties because it is virtually impossible to complete all phases of investigation within thirty days of receipt of a referral.

The second item pertains to Section 26(a)(3). EPA has interpreted this provision to mean that States must be accountable to EPA on a case-by-case basis in the implementation of primacy use enforcement. Such an approach by EPA to oversight of State activities requires an inordinant amount of time on the part of State officials, and does not accomplish any more effective oversight than periodic programmatic review of State enforcement actions.

Both NASDA and the Association of American Pesticide Control Officials have testified on these two enforcement issues on previous occasions, and we take this occasion to call your attention to them once again.

In summary, Mr. Chairman, we respectfully urge the Committee to report a simple, two-year reauthorization of existing FIFRA authorities, and including a five year reauthorization of the Scientific Advisory Panel.

Mr. Chairman, the Association appreciate this opportunity to present our views, and we look forward to assisting you in any way we can.

II

98TH CONGRESS
1ST SESSION

S. 1263

To amend and extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for two years.

IN THE SENATE OF THE UNITED STATES

MAY 11 (legislative day, MAY 9), 1983

Mr. HELMS (by request) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

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A BILL

To amend and extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for two years.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136w), is amended by striking "September 30, 1981" and inserting in lieu thereof "September 30, 1988".

SEC. 2. Section 31 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136y), is amended by adding at the end thereof the following new sentence: "There are hereby authorized to be appropriated to carry out the provisions of this Act for the period beginning October 1, 1983, and ending September 30, 1984, $46,624,400 and for the period beginning October 1, 1984, and ending September 30, 1985, such sums as may be necessary.".

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